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ABSTRACT

This handbook is intended to provide pharmacists, pharmacy students, and other interested persons with general information and with the text of various laws, rules, and regulations governing pharmacy licensure, the practice of the profession of pharmacy, and the purity, potency, labeling, manufacture, distribution, and sale of drugs in New York State. It includes excerpts from the text of provisions of the Education Law, the rules of the Board of Regents, the regulations of the Commissioner of Education, and the rules of the State Board of Pharmacy. Appended materials include information on pharmacy examinations, a selected list of other laws governing the practice of pharmacy, and a list of accredited colleges of pharmacy in New York State. (SW)

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HANDBOOK 11

Professional Education

pharmacy

Law Rules Information

(as in effect on
September 1, 1979)

The University of the State of New York
THE STATE EDUCATION DEPARTMENT
Albany, New York 12230

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INTRODUCTION

This handbook is intended to provide pharmacists, pharmacy students and other interested persons with general information and with the text of various laws, rules and regulations governing pharmacy licensure, the practice of the profession of pharmacy and the purity, potency, labeling, manufacture, distribution and sale of drugs in New York State. It includes excerpts from the text of provisions of the Education Law, the Rules of the Board of Regents, the Regulations of the Commissioner of Education and the Rules of the State Board of Pharmacy. It does not include other relevant Federal and State laws, rules and regulations. A selected list of these is included in the Appendix.

Nature of the Profession of Pharmacy

The scope of the profession of pharmacy is defined in Section 6801 of the Education Law of the State of New York as follows:

"The practice of the profession of pharmacy is defined as the preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority."

The professional responsibilities encompassed within that brief definition are constantly expanding as a result of changes in the health care field. One such recent development of particular concern to pharmacists and to the public is the role which pharmacists may play in monitoring drug use by maintaining patient medication profiles. The profile may indicate a potentially harmful combination of drugs. These drugs may be either prescription required, prescribed by different physicians, or drugs for which a prescription is not required. A second such recent development is the role of the pharmacist in helping to reduce health care costs by the selection and dispensing of therapeutically equivalent generic drugs instead of more expensive brand name drugs. Pharmacists may also counsel patients on matters which fall within their competence such as the instructions for use of a drug and storage requirements. Many pharmacists are involved in activities such as research, testing for quality control, manufacturing or distribution of drugs.

Authorization to Practice Pharmacy

Only a person licensed or exempted from the licensing statute may legally perform or offer to perform acts which come within the scope of the statutory definition of practice or use the title "pharmacist" (Education Law sections 6512, 6513, 6803 and 6811).

A limited permit authorizing practice by a "pharmacy intern" under the immediate and personal supervision of a licensed pharmacist may be issued to advanced pharmacy students and graduates of pharmacy programs (id. section 6806).

Exemptions from the licensing requirement include other health professionals practicing within the scope of their respective professions (id. sections 6505 and 6807).

The requirements and procedures for obtaining a pharmacy license are set forth in section 6805 of the Education Law and in sections 63.1 and 63.2 of the Regulations of the Commissioner of Education.

A licensee must register biennially with the Education Department to practice in this State. Registration is accomplished by the submission of an application accompanied by the statutory fee (id. section 6502).

Questions relating to the application for admission to the licensing examination or to the biennial registration of pharmacists should be directed to the Division of Professional Licensing Services, Cultural Education Center, Albany, New York 12230.

Registration of Establishments

Registration by the Education Department is required of all persons (individuals, partnerships or corporations) who possess drugs, prescriptions or poisons for the purpose of compounding, dispensing, retailing, wholesaling or manufacturing or who offer such materials for sale at retail or wholesale. The Department registers pharmacies, wholesalers, manufacturers and stores (Education Law section 6808).

Pharmacies may be owned by unlicensed persons or corporations provided that the actual practice of pharmacy is conducted by licensed pharmacists. A separate registration is required for each pharmacy. A licensed pharmacist must be designated formally as the "supervising pharmacist" for each pharmacy. Such pharmacist is personally responsible for the conduct of the practice of pharmacy at

the specified pharmacy and for insuring compliance with all applicable laws, rules and regulations.

The owners of manufacturing and wholesaling establishments are not required to be pharmacists. Evidence satisfactory to the Department must be submitted indicating that the owners or their employees are competent to carry out the activities covered by the registration.

Questions relating to the registration of establishments should be directed to the Board of Pharmacy, Cultural Education Center, Albany, New York 12230. Tel. (518) 474-7740.

Enforcement Proceedings

Complaints of alleged violations of the laws, rules and regulations governing the practice of pharmacy or the purity, potency, labeling, manufacture, distribution and sale of drugs should be submitted in writing to the Executive Secretary of the State Board of Pharmacy. They will be investigated by the Department and further action will be taken in appropriate cases.

Legal proceedings to restrain the performance of illegal acts may be brought by the Attorney General (Education Law section 6515) or, in some cases, by the Executive Secretary of the State Board of Pharmacy (id. section 6824). Proceedings directed to the seizure of drugs may be brought by the State Board of Pharmacy (id. section 6813).

Various types of misconduct are defined as misdemeanors in the Law. Criminal charges may be brought against the offenders.

Civil disciplinary proceedings against pharmacists, pharmacy interns, pharmacies, manufacturers and wholesalers may be brought under either section 6809 or section 6510 of the Education Law. The former section provides a more expeditious means of discipline for minor and technical violations. It may result in a monetary penalty of not more than \$500 for each violation.

Disciplinary proceedings under section 6510 of the Education Law may result in any of the measures of discipline, including revocation or suspension of a license or certificate of registration, authorized by section 6511.

STATUTORY PROVISIONS

Education Law

[As amended to the close of legislation, 1979]

TITLE VIII OF THE EDUCATION LAW

ARTICLE 130: GENERAL PROVISIONS

SUBARTICLE 1. INTRODUCTORY SUMMARY

§ 6500. **Introduction.** This title provides for the regulation of the admission to and the practice of certain professions. This first article applies to all the professions included in this title, except that prehearing procedures and hearing procedures in connection with the regulation of professional conduct of the profession of medicine shall be conducted pursuant to the provisions of Title II-A of article two of the public health law. Each of the remaining articles applies to a particular profession.

§ 6501. **Admission to a profession (licensing).** Admission to practice of a profession in this state is accomplished by a license being issued to a qualified applicant by the education department. To qualify for a license an applicant shall meet the requirements prescribed in the article for the particular profession.

§ 6502. **Duration and registration of a license.** 1. A license shall be valid during the life of the holder unless revoked, annulled or suspended by the board of regents. A licensee must register biennially with the department to practice in this state.

2. The department shall establish the beginning dates of the two-year registration for each profession and mail an application for registration to every licensee currently registered at least four months prior to the beginning of the registration period for the respective profession.

3. An application for registration and the required registration fee shall be submitted with or as part of the application for a license. A person initially licensed or a licensee resuming practice after a lapse of registration in the last four months of a two-year registration period shall be registered for the succeeding registration period without an additional registration fee. The department shall renew

the registration of each licensee upon receipt of a proper application, on a form prescribed by the department, and the registration fee. Any licensee who fails to register by the beginning of the appropriate registration period shall be required to pay an additional fee for late filing of five dollars for each month that registration has been delayed while such licensee continued to practice his profession. The licensee resuming practice after a lapse of registration shall be permitted to practice without actual possession of the registration certificate for not more than four months after mailing to the department the required application fee.

4. Any licensee who is not engaging in the practice of his profession in this state and does not desire to register shall so advise the department. Such licensee may subsequently register and resume practice without paying an additional fee for failure to register at the beginning of the registration period.

5. Licensees shall notify the department of any change of name or mailing address within thirty days of such change.

§ 6503. **Practice of a profession.** Admission to the practice of a profession (1) entitles the licensee to practice the profession as defined in the article for the particular profession, (2) entitles the individual licensee to use the professional title as provided in the article for the particular profession, and (3) subjects the licensee to the procedures and penalties for professional misconduct as prescribed in this article (sections sixty-five hundred nine, sixty-five hundred ten, and sixty-five hundred eleven).

§ 6504. **Regulation of the professions.** Admission to the practice of the professions (licensing) and regulation of such practice shall be supervised by the board of regents (section sixty-five hundred six) and administered by the education department (section sixty-five hundred seven) assisted by a state board for each profession (section sixty-five hundred eight).

§ 6505. **Construction.** No definition of the practice of a profession shall be construed to restrain or restrict the performance of similar acts authorized in the definition of other professions.

SUBARTICLE 2. STATE MANAGEMENT

§ 6506. **Supervision by the board of regents.** The board of regents shall supervise the admission to and the practice of the professions. In supervising, the board may:

- (1) Promulgate rules;

- (2) Establish by rule, high school, preprofessional, professional and other educational qualifications required for licensing in the professions regulated by this title;
- (3) Charter schools offering educational programs for the professions regulated by this title, and no such school shall operate in this state without such a charter, except Columbia University, any school chartered by special act of the legislature prior to September one, nineteen hundred seventy-one, and schools specifically authorized to conduct such programs by the regents;
- (4) Appoint such committees as it deem necessary and compensate members of such committees who are not members of the board of regents or the department up to one hundred dollars per day for each day devoted to committee functions, together with their necessary expenses;
- (5) Waive education, experience and examination requirements for a professional license prescribed in the article relating to the profession, provided the board of regents shall be satisfied that the requirements of such article have been substantially met;
- (6) Indorse a license issued by a licensing board of another state or country upon the applicant fulfilling the following requirements:
 - (a) Application: file an application with the department;
 - (b) Education: meet educational requirements in accordance with the commissioner's regulations;
 - (c) Experience: have experience satisfactory to the board and in accordance with the commissioner's regulations;
 - (d) Examination: pass an examination satisfactory to the board and in accordance with the commissioner's regulations;
 - (e) Age: be at least twenty-one years of age;
 - (f) Citizenship: be a United States citizen, or file a declaration of intention to become a citizen, unless such requirement is waived, in accordance with the commissioner's regulations;
 - (g) Character: be of good moral character as determined by the department; and
 - (h) Fees: pay a fee to the department for indorsement of forty dollars.

- (7) Direct the department to remedy any error, omission, delay or other circumstance in the issuance or registration of a license;
- (8) Designate a professional conduct officer on recommendation of the commissioner in connection with professional licensing and misconduct proceedings and criminal matters, such officer to be empowered to issue subpoenas and administer oaths in connection with such proceedings;
- (9) Establish by rule, standards of conduct with respect to advertising, fee splitting, practicing under a name other than that of the individual licensee (when not specifically authorized), proper use of academic or professional degrees or titles tending to imply professional status, and such other ethical practices as such board shall deem necessary; and
- (10) Delegate to department officers the disposition of any licensing matters pursuant to rules.

§ 6507. **Administration by the education department.** 1. The commissioner and the department shall administer the admission to and the practice of the professions.

2. In administering, the commissioner may:
 - a. Promulgate regulations;
 - b. Conduct investigations;
 - c. Issue subpoenas;
 - d. Grant immunity from prosecution in accordance with section 50.20 of the criminal procedure law to anyone subpoenaed in any investigation or hearing conducted pursuant to this title; and
 - e. Excuse, for cause acceptable to the commissioner, the failure to register biennially. Such excuse shall validate and authorize such practitioner's right to practice pending registration.
3. The department assisted by the board for each profession, shall:
 - a. Establish standards for preprofessional and professional education, experience and licensing examinations as required to implement the article for each profession;
 - b. Review qualifications in connection with licensing requirements; and
 - c. Provide for licensing examinations and reexaminations.
4. The department shall:

a. Register or approve educational programs designed for the purpose of providing professional preparation which meet standards established by the department;

b. Issue licenses, registrations, and limited permits to qualified applicants;

c. (i) Issue a certificate of authority to a qualified professional service corporation being organized under section fifteen hundred three of the business corporation law on payment of a fee of twenty-five dollars. (ii) File a certified copy of each certificate of incorporation and amendment thereto within thirty days after the filing of such certificate or amendment on payment of a fee of ten dollars. (iii) File the annual statement required by section fifteen hundred fourteen of the business corporation law on payment of a fee of ten dollars.

d. Revoke limited permits on the recommendation of the committee on professional conduct for the profession concerned;

e. Maintain public records of licenses issued and retain in its files identifying data concerning each person to whom a license has been issued; and

f. Collect the fees prescribed by this title or otherwise provided by law.

5. The commissioner and the department shall perform any other functions necessary to implement this title.

§ 6508. Assistance by state boards for the professions. 1. A board for each profession shall be appointed by the board of regents on the recommendation of the commissioner for the purpose of assisting the board of regents and the department on matters of professional licensing, practice and conduct. The composition of each board shall be as prescribed in the article relating to each profession. Within each board a committee on licensing and one or more committees on professional conduct may be appointed by the board chairman. Except as provided in paragraph (a) of this subdivision, the membership of each professional licensing board shall be increased by one member, and each such board shall have at least one public representative who shall be selected by the board of regents from the general public.

a. The membership of the professional licensing boards created under sections sixty-five hundred twenty-three, sixty-eight hundred four, sixty-nine hundred three, and seventy-four hundred three of this chapter shall be increased by two members, and each such

board shall have at least two public representatives, who shall be selected by the board of regents from the general public.

b. For the purposes of this title, a "public representative" shall be a person who is a consumer of services provided by those licensed or otherwise supervised or regulated by the boards created hereunder, and shall not be, nor within five years immediately preceding appointment have been:

(i) a licensee or person otherwise subject to the supervision or regulation of the board to which appointed; or

(ii) a person maintaining a contractual relationship with a licensee of such board, which would constitute more than two per centum of the practice or business of any such licensee, or an officer, director, or representative of such person or group of persons.

2. Each board, or its committee on licensing, shall select or prepare examinations, may conduct oral and practical examinations and reexaminations, shall fix passing grades, and assist the department in other licensing matters as prescribed by the board of regents.

3. Each board, or its committee or committees on professional conduct, shall conduct disciplinary proceedings as prescribed in this article and shall assist in other professional conduct matters as prescribed by the board of regents. Former members of each board may be reappointed by the board of regents, on the recommendation of the commissioner, to serve as members of the board and of its committee or committees on professional conduct for the sole purpose of conducting disciplinary proceedings pursuant to this article. Former board members so appointed may not comprise a majority of any hearing panel.

4. Members of each board shall be appointed by the board of regents for five-year terms except that the terms shall be arranged so that as nearly as possible an equal number shall terminate annually. A vacancy occurring during a term shall be filled by an appointment by the board of regents for the unexpired term. Each state professional association or society may nominate one or more candidates for each appointment to be made to the board for its profession, but the board of regents shall not be required to appoint candidates so nominated.

5. Each member of a board shall receive a certificate of appointment, shall before beginning his term of office file a constitutional

oath of office with the secretary of state, shall receive up to one hundred dollars as prescribed by the board of regents for each day devoted to board work, and shall be reimbursed for his necessary expenses. No member shall serve beyond the age of seventy. Any member may be removed from a board by the board of regents for misconduct, incapacity or neglect of duty.

6. Each board shall elect from its members a chairman and vice-chairman annually, shall meet upon call of the chairman or the department, and may adopt bylaws consistent with this title and approved by the board of regents. A quorum for the transaction of business by the board shall be a majority of members but not less than five members.

7. An executive secretary to each board shall be appointed by the board of regents on recommendation of the commissioner. Such executive secretary shall not be a member of the board, shall hold office at the pleasure of, and shall have the powers, duties and annual salary prescribed by the board of regents.

SUBARTICLE 3. PROFESSIONAL MISCONDUCT

§ 6509. **Definitions of professional misconduct.** Each of the following is professional misconduct, and any licensee found guilty of such misconduct under the procedures prescribed in section sixty-five hundred ten shall be subject to the penalties prescribed in section sixty-five hundred eleven:

- (1) Obtaining the license fraudulently.
- (2) Practicing the profession fraudulently, beyond its authorized scope, with gross incompetence, with gross negligence on a particular occasion or negligence, or incompetence on more than one occasion,
- (3) Practicing the profession while the ability to practice is impaired by alcohol, drugs, physical disability, or mental disability,
- (4) Being habitually drunk or being dependent on, or a habitual user of narcotics, barbiturates, amphetamines, hallucinogens, or other drugs having similar effects,
- (5) Being convicted of committing an act constituting a crime under:
 - (a) New York State law or,
 - (b) Federal law or,
 - (c) The law of another jurisdiction and which, if committed

within this state, would have constituted a crime under New York State law.

(6) Refusing to provide professional service to a person because of such person's race, creed, color, or national origin,

(7) Permitting, aiding or abetting an unlicensed person to perform activities requiring a license,

(8) Practicing the profession while the license is suspended, or, wilfully failing to register or notify the department of any change of name or mailing address, or, a professional service corporation wilfully failing to comply with sections fifteen hundred three and fifteen hundred fourteen of the business corporation law,

(9) Committing unprofessional conduct, as defined by the board of regents in its rules or by the commissioner in regulations approved by the board of regents, or

(10) A willful violation by a licensed physician of subdivision eleven of section two hundred thirty of the public health law.

§ 6509a. **Additional definition of professional misconduct; limited application.** Notwithstanding any inconsistent provisions of this article or of any other provision of law to the contrary, the license or registration of a person subject to the provisions of articles one hundred thirty-one, one hundred thirty-one-a, one hundred thirty-three, one hundred thirty-seven, one hundred thirty-nine, one hundred forty-one, one hundred forty-three, one hundred forty-four, one hundred fifty-six and one hundred fifty-nine of this chapter may be revoked, suspended or annulled or such person may be subject to any other penalty provided in section sixty-five hundred eleven of this article in accordance with the provisions and procedure of this article for the following:

That any person subject to the above enumerated articles, has directly or indirectly requested, received or participated in the division, transference, assignment, rebate, splitting or refunding of a fee for, or has directly requested, received or profited by means of a credit or other valuable consideration as a commission, discount or gratuity in connection with the furnishing of professional care, or service, including x-ray examination and treatment, or for or in connection with the sale, rental, supplying or furnishing of clinical laboratory services or supplies, x-ray laboratory services or supplies, inhalation therapy service or equipment, ambulance service, hospital or medical supplies, physiotherapy or other therapeutic service or equipment, artificial limbs, teeth or eyes, orthopedic or surgical

appliances or supplies, optical appliances, supplies or equipment, devices for aid of hearing, drugs, medication or medical supplies or any other goods, services or supplies prescribed for medical diagnosis, care or treatment under this chapter, except payment, not to exceed thirty-three and one-third per centum of any fee received for x-ray examination, diagnosis or treatment. Nothing contained in this section shall prohibit such persons from practicing as partners, in groups or as a professional corporation nor from pooling fees and moneys received, either by the partnerships, professional corporations or groups by the individual members thereof, for professional services furnished by an individual professional member, or employee of such partnership, corporation or group, nor shall the professionals constituting the partnerships, corporations or groups be prohibited from sharing, dividing or apportioning the fees and moneys received by them or by the partnership, corporation or group in accordance with a partnership or other agreement; provided that no such practice as partners, corporations or in groups or pooling of fees or moneys received or shared, division or apportionment of fees shall be permitted with respect to care and treatment under the workmen's compensation law except as expressly authorized by the workmen's compensation law. Nothing contained in this chapter shall prohibit a medical or dental expense indemnity corporation pursuant to its contract with the subscriber from prorationing a medical or dental expense indemnity allowance among two or more professionals in proportion to the services rendered by each such professional at the request of the subscriber, provided that prior to payment thereof such professionals shall submit both to the medical or dental expense indemnity corporation and to the subscriber statements itemizing the services rendered by each such professional and the charges therefor.

§ 6510. **Proceedings in cases of professional misconduct.** In cases of professional misconduct the proceedings shall consist of (1) prehearing procedures by the education department, (2) hearing procedures by the committee on professional conduct for the particular profession, (3) decision procedures by the board of regents, and (4) review procedures by the appellate division of the third judicial department, as follows:

1. Prehearing procedures.

a. Complaint. A complaint of a licensee's professional misconduct may be made by any person to the education department. (N.B. There are two paragraphs lettered "b" in the Law.)

b. [See also par. b set out below] Investigation. The department shall investigate each complaint. The results of the investigation shall be referred to the professional conduct officer designated by the board of regents. If such officer decides that a hearing is warranted, on the basis of an alleged violation of subdivision five of section sixty-five hundred nine of this article, he shall request the attorney general to prepare the charges. If such officer decides that a hearing is warranted on the basis of an alleged violation of other or additional charges of professional misconduct he shall refer the matter to a panel of three or more members of the committee on professional conduct for the particular profession. If such panel agrees that a hearing is warranted, the department shall request the attorney general to prepare the charges.

b. [See also, par. b set out above] Investigation. The department shall investigate each complaint and if the department and the committee on professional conduct for the particular profession decide that a hearing is warranted, the department shall request the attorney general to prepare the charges. If the professional conduct officer and the committee on professional conduct agree that there is substantial evidence of misconduct, but that such misconduct is of a minor or technical nature, the investigation may be terminated by the issuance of an administrative warning by the professional conduct officer. Such warnings shall be confidential and shall not constitute an adjudication of guilt or be used as evidence that the licensee is guilty of the alleged misconduct. However in the event of a further charge of similar misconduct by the same licensee the investigation may be reopened and further proceedings instituted as provided in this section.

c. Charges. Upon such request the attorney general shall prepare the charges if he decides that a hearing is warranted. The charges shall state the alleged professional misconduct and shall state concisely the material facts but not the evidence by which the charges are to be proved.

d. Notice of hearing. The department shall set the time and place of the hearing and shall prepare the notice of hearing. The notice of hearing shall state (1) the time and place of the hearing, (2) that the licensee may file a written answer to the charges prior to the hearing, (3) that the licensee shall appear personally at the hearing and may be represented by counsel, (4) that the licensee shall have the right to produce witnesses and evidence in his behalf, to cross-examine witnesses and examine evidence produced against

him, and to have subpoenas issued in his behalf to require the production of witnesses and evidence in manner and form as prescribed by the civil practice law and rules, (5) that a stenographic record of the hearing will be made, and (6) such other information as may be considered appropriate by the department.

e. Service of charges and of notice of hearing. A copy of the charges and the notice of hearing shall be served on the licensee personally by the department at least fifteen days before the hearing. If personal service cannot be made after due diligence and such fact is certified under oath, a copy of the charges and the notice of hearing shall be served by registered mail to the licensee's last known address by the department at least twenty days before the hearing.

2. Hearing procedures.

a. Hearing panel. The hearing shall be conducted by a panel of five or more members of the committee on professional conduct for the particular profession. The panel shall be appointed by the committee chairman who shall designate the panel chairman.

b. Conduct of hearing. The evidence in support of the charges shall be presented by the attorney general or his designee. The licensee shall have the rights required to be stated in the notice of hearing (subparagraph d of subdivision one of this section). The panel shall not be bound by the rules of evidence, but its determination of guilt shall be based on substantial legal evidence.

c. Results of hearing. As a result of the hearing the panel (1) shall make findings of fact, (2) shall make a determination of guilty or not guilty on each charge, and (3) in the event of a determination of guilty, shall make a recommendation of the penalty to be imposed. For the panel to make a determination of guilty, a minimum of four-fifths of the panel must vote for such a determination.

d. Disposition of results. The panel shall transmit to the board of regents the transcript of the hearing and results of the hearing and shall transmit to the licensee the results of the hearing unless the board shall have established a bylaw providing for a review of the record of findings and determination of the panel by the committee on professional misconduct. If such review is required, the committee shall review the record and transcript of the hearing and make a finding and recommendation by a four-fifths vote. The transcript and results of the hearing and the findings and recommendation of the committee shall then be transmitted to the board of regents. The licensee shall be advised of the results.

3. Regents decision procedures.

a. Regents review committee. The transcript and results of the hearing and the recommendation, if any, of the committee shall be reviewed at a meeting by a committee appointed by the board of regents. The committee shall consist of three members, at least one of whom shall be a regent.

b. Review committee meetings. The review shall be based on the transcript, results of the hearing and the recommendation, if any, of the committee, but the licensee may appear at the meeting, and the review committee may require him to appear. The licensee may be represented by counsel. The review committee shall notify the licensee at least seven days before the meeting (1) of the time and place of the meeting, (2) of his right to appear, (3) of his right to be represented by counsel, (4) whether or not he is required to appear, and (5) of such other information that may be considered appropriate. After the meeting the committee shall transmit a written report of its review to the board of regents.

c. Regents decision and order. The board of regents (1) shall consider the transcript, results of the hearing and recommendation, if any, of the committee and the report of its review committee, (2) shall decide whether the licensee is guilty or not guilty on each charge, (3) shall decide what penalties, if any, to impose as prescribed in section sixty-five hundred eleven of this article, and (4) shall issue an order to carry out its decisions. Such decisions shall require the affirmative vote of a majority of the members of the board. If the board disagrees with the hearing panel's determination of not guilty, it shall remand the matter to the panel for a new hearing after which the panel's determination of not guilty shall be final. The order shall be served upon the licensee personally or by certified mail to the licensee's last known address and such service shall be effective as of the date of the personal service or five days after mailing by certified mail. The licensee shall deliver to the department the license and registration certificate which has been revoked, annulled, suspended, or surrendered within five days after the effective date of the service of the order. If the license or registration certificate is lost, misplaced or its whereabouts is otherwise unknown, the licensee shall submit an affidavit to that effect, and shall deliver such license or certificate to the department when located.

4. Court review procedures. The decisions of the board of regents may be reviewed pursuant to the proceedings under article

seventy-eight of the civil practice laws and rules. Such proceedings shall be returnable before the appellate division of the third judicial department, and such decisions shall not be stayed or enjoined except upon application to such appellate division after notice to the attorney general.

5. The provisions of this section shall not be applicable to proceedings in cases of professional misconduct involving the medical profession.

§ 6511. **Penalties for professional misconduct.** The penalties which may be imposed by the board of regents on a present or former licensee found guilty of professional misconduct (under the definitions and proceedings prescribed in sections sixty-five hundred nine, sixty-five hundred ten and sixty-five hundred ten-a of this article) are: (1) censure and reprimand, (2) suspension of license, (a) wholly, for a fixed period of time; (b) partially, until the licensee successfully completes a course of retraining in the area in which the suspension applies; (c) wholly, until the licensee successfully completes a course of therapy or treatment prescribed by the regents; (3) revocation of license, (4) annulment of license or registration, (5) limitation on registration or issuance of any further license, and (6) a fine not to exceed five thousand dollars. The board of regents may stay such penalties and place the licensee on probation and may restore a license which has been revoked.

SUBARTICLE 4. UNAUTHORIZED ACTS

§ 6512. **Unauthorized practice a crime.** 1. Anyone not authorized to practice under this title who practices or offers to practice or who holds himself out as being able to practice in any profession in which a license is a prerequisite to the practice of the acts, or who practices any profession as an exempt person during the time when his professional license is suspended, revoked or annulled, or who aids or abets an unlicensed person to practice a profession, or who fraudulently sells, files, furnishes, obtains, or who attempts fraudulently to sell, file, furnish or obtain any diploma, license, record or permit purporting to authorize the practice of a profession, shall be guilty of a class E felony.

2. Anyone who knowingly aids or abets three or more unlicensed persons to practice a profession or employs or holds such unlicensed persons out as being able to practice in any profession in

which a license is a prerequisite to the practice of the acts, or who knowingly aids or abets three or more persons to practice any profession as exempt persons are suspended, revoked or annulled, shall be guilty of a class E felony.

§ 6513. Unauthorized use of a professional title a crime. 1. Anyone not authorized to use a professional title regulated by this title, and who uses such professional title, shall be guilty of a class A misdemeanor.

2. Anyone who knowingly aids or abets three or more persons not authorized to use a professional title regulated by this title, to use such professional title, or knowingly employs three or more persons not authorized to use a professional title regulated by this title, who use such professional title in the course of such employment, shall be guilty of a class E felony.

§ 6514. Criminal proceedings. 1. All alleged violations of section sixty-five hundred twelve or sixty-five hundred thirteen of this article shall be reported to the department which shall cause an investigation to be instituted. If the investigation substantiates that violations exist, such violations shall be reported to the attorney general with a request for prosecution.

2. The attorney general shall prosecute such alleged offenses in the name of the state provided, however, in the event of alleged violations of article one hundred fifty-five of this title occurring in cities with a population of one million or more, a district attorney may prosecute such alleged offenses in the name of the state, provided, however, that any district attorney may prosecute such offenses where they are incidental to a criminal prosecution instituted by him under other statutes.

3. All criminal courts having jurisdiction over misdemeanors are hereby empowered to hear, try and determine alleged violations under this title, which constitute misdemeanors, without indictment and to impose applicable punishment of fines or imprisonments or both. It shall be necessary to prove in any prosecution under this title only a single prohibited act or a single holding out without proving a general course of conduct.

4. A proceeding before a committee on professional conduct shall not be deemed to be a criminal proceeding within the meaning of this section.

§ 6515. **Restraint of unlawful acts.** Where a violation of this title is alleged to have occurred, the attorney general or, in the event of alleged violations of article one hundred fifty-five of this title occurring in cities having a population of one million or more, the corporation counsel may apply to the supreme court within the judicial district in which such violation is alleged to have occurred for an order enjoining or restraining commission or continuance of the unlawful acts complained of. The court shall have jurisdiction of the proceedings and shall have power to grant such temporary relief or restraining order as it deems just and proper. In any such proceeding it shall be unnecessary to allege or prove that an adequate remedy at law does not exist or that irreparable damage would result if such order were not granted. The remedy provided in this section shall be in addition to any other remedy provided by law or to the proceedings commenced against a licensee under this title.

ARTICLE 137: PHARMACY

§ 6800. **Introduction.** This article applies to the profession of pharmacy. The general provisions for all professions contained in article one hundred thirty of this title apply to this article.

§ 6801. **Definition of practice of pharmacy.** The practice of the profession of pharmacy is defined as the preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority.

§ 6802. **Definitions.** 1. "Pharmacy" means any place, other than a registered store, in which drugs, prescriptions or poisons are possessed for the purpose of compounding, preserving, dispensing or retailing, or in which drugs, prescriptions or poisons are compounded, preserved, dispensed or retailed, or in which such drugs, prescriptions or poisons are by advertising or otherwise offered for sale at retail.

2. "Registered store" means a store for which a storekeeper's license has been issued, located in a village or place of less than one thousand inhabitants that has no pharmacy within three miles.

3. "Formulary" means the latest edition of the official national formulary, and its supplement.

4. "Pharmacopeia," when not otherwise limited, means the latest edition of the official United States pharmacopeia, and its supplement.

5. "Homeopathic pharmacopeia" means the official homeopathic pharmacopeia of the United States, and its supplement.

6. "Official compendium" means the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, or official national formulary or their supplements.

7. "Drugs" means:

a. Articles recognized in the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, or official national formulary.

b. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals.

c. Articles (other than food) intended to affect the structure or any function of the body of man or animals.

d. Articles intended for use as a component of any article specified in paragraphs a, b, or c; but does not include devices or their components, parts or accessories.

8. "Cosmetics" means:

a. Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.

b. Articles intended for use as a component of any such articles; except that the term shall not include soap.

9. "Poison," where not otherwise limited, means any drug, chemical or preparation likely to be destructive to adult human life in quantity of sixty grains or less.

10. "Label" means a display of written, printed or pictorial matter upon the immediate container of any drug, device or cosmetic. Any requirement made by or under authority of this article, that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if there be any, of the retail package of such drug, device or cosmetic or is easily legible through the outside container or wrapper.

11. "Immediate container" does not include package liners.

12. "Labeling" means all labels and other written, printed or pictorial matter:

a. Upon any drug, device or cosmetic or any of its containers or wrappers, or

b. Accompanying such drug, device or cosmetic.

13. "Misbranding." A drug, device or cosmetic is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading then in determining whether the labeling or advertisement is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the drug, device, or cosmetic to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual. No drug, device or cosmetic which is subject to, and complies with regulations promulgated under the provisions of the federal food, drug, and cosmetic act, relating to adulteration and misbranding shall be deemed to be adulterated or misbranded in violation of the provisions of this article because of its failure to comply with the board's regulations, or the rules of the state board of pharmacy, insofar as the regulations are in conflict with regulations relating to adulteration and misbranding under the federal food, drug and cosmetic act.

14. "Antiseptic." The representation of a drug, device or cosmetic in its labeling, as an antiseptic, shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

15. "New drug" means:

a. Any drug not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested by the drug's labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to September first, nineteen hundred thirty-nine it was subject to the former federal food and drug act of June thirtieth, nineteen hundred six, as amended, and if

at such time its labeling contained the same representations concerning the conditions of its use;

b. Any drug, the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become recognized, but which has not otherwise than in such investigations been used to a material extent or for a material time under such conditions.

16. "Device" means instruments, apparatus, and contrivances, including their components, parts and accessories, intended:

a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; or

b. To affect the structure of any function of the body of man or animals.

17. The term "Federal Food, Drug and Cosmetic Act" means the Federal Food, Drug, and Cosmetic Act of the United States of America, approved June twenty-fifth, nineteen hundred thirty-eight, officially cited as public document number seven hundred seventeen-seventy-fifth congress (chapter six hundred seventy-five—third session), and all its amendments now or hereafter enacted.

18. "Wholesaler" means a person who bottles, packs or purchases drugs, devices or cosmetics for the purpose of selling or reselling to pharmacies or to other channels as provided in this article.

19. "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs, devices or cosmetics.

20. "Controlled substance" means any drug defined as a controlled substance by article thirty-three of the public health law.

21. "Manufacturer" means a person who compounds, mixes, prepares, produces, and bottles or packs drugs, cosmetics or devices for the purpose of distributing or selling to pharmacies or to other channels of distribution.

§ 6803. **Practice of pharmacy and use of title "pharmacist."** Only a person licensed or otherwise authorized under this article shall practice pharmacy or use the title "pharmacist" or any derivative.

§ 6804. **State board of pharmacy.** A state board of pharmacy shall be appointed by the regents on recommendation of the com-

missioner for the purpose of assisting the regents and the department on matters of professional licensing and professional conduct in accordance with section sixty-five hundred eight of this title. The board shall be composed of not less than nine pharmacists licensed in this state for at least five years. An executive secretary to the board shall be appointed by the regents on recommendation of the commissioner and shall be a pharmacist licensed in this state for at least five years. The board shall have power:

- a. To regulate the practice of pharmacy and the employment of interns and employees in pharmacies,
- b. To regulate and control the sale, distribution, character and standard of drugs, poisons, cosmetics, devices and new drugs,
- c. To employ inspectors and chemists,
- d. To prevent the sale or distribution of such drugs, poisons, cosmetics, devices and new drugs as do not conform to the provisions of this article or of the public health law,
- e. To investigate alleged violations of the provisions of this article through its own investigative personnel or those of other agencies, to conduct hearings, to levy money penalties, and to bring alleged violations to the notice of the attorney general, and
- f. To issue limited permits or registrations.

§ 6805. **Requirements for a professional license.** 1. To qualify for a pharmacist's license, an applicant shall fulfill the following requirements:

- (1) Application: file an application with the department;
- (2) Education: have received an education, including a bachelor's or equivalent degree in pharmacy, in accordance with the commissioner's regulations;
- (3) Experience: have experience satisfactory to the board and in accordance with the commissioner's regulations;
- (4) Examination: pass an examination satisfactory to the board and in accordance with the commissioner's regulations;
- (5) Age: be at least twenty-one years of age;
- (6) Citizenship: be a United States citizen, or file a declaration of intention to become a citizen in accordance with the commissioner's regulations;
- (7) Character: be of good moral character as determined by the department; and
- (8) Fees: pay a fee of eighty dollars to the department for admission to a department conducted examination and for an initial license, a fee of forty dollars for each re-examination, a fee of fifty

dollars for an initial license for persons not requiring admission to a department conducted examination, and a fee of thirty dollars for each biennial registration.

2. On or before April first, nineteen hundred seventy-two, any person who holds a valid license as "druggist" in this state shall make application and on the payment of fees specified in this title be licensed by the department as a pharmacist. Such person shall have all of the rights, privileges, duties and responsibilities of a pharmacist.

§ 6806. **Limited permits.** 1. The department may issue a limited permit for employment as a "pharmacy intern" to:

a. A student enrolled in the last two years of a registered program in pharmacy, or

b. A graduate of a program in pharmacy which meets standards established by the commissioner's regulations who is engaged in meeting the experience requirements or whose application for initial licensure is pending with the department.

2. A pharmacy intern may, as determined by the commissioner's regulations, practice as a pharmacist under the immediate personal supervision of a licensed pharmacist.

3. A limited permit issued to a pharmacy intern shall have an expiration date of five years from the date of issue. Limited permits may be renewed once for a period not to exceed two years.

4. Fees. The fee for each limited permit issued to a pharmacy intern shall be twenty dollars.

§ 6807. **Exempt persons.** 1. This article shall not be construed to affect or prevent:

a. Unlicensed assistants from being employed in licensed pharmacies for purposes other than the practice of pharmacy;

b. Any physician, dentist or veterinarian who is not the owner of a pharmacy, or registered store, or who is not in the employ of such owner, from supplying his patients with such drugs as the physician, dentist or veterinarian deems proper in connection with his practice, provided, however, that all such drugs shall be dispensed in a container labeled with the name and address of the dispenser and patient, directions for use, and date of delivery, and in addition, such drug shall bear a label containing the proprietary or brand name of the drug and, if applicable, the strength of the

contents, unless the person issuing the prescription specifically states on the prescription in his own handwriting, that the name of the drug and the strength thereof should not appear on the label; provided further that if such drugs are controlled substances, they shall be dispensed pursuant to the requirements of article thirty-three of the public health law;

c. Any merchant from selling proprietary medicines, except those which are poisonous, deleterious or habit forming, or materials and devices specifically exempted by regulations of the department or by the public health law;

d. Any personnel in an institution of higher learning from using prescription-required drugs on the premises for authorized research, experiments or instruction, in accordance with the department's regulations and, if such drugs are controlled substances, in accordance with Title III of article thirty-three of the public health law; or

e. The necessary and ordinary activities of manufacturers and wholesalers, subject to the provisions of article thirty-three of the public health law.

§ 6808. **Registering and operating establishments.** 1. No person, firm, corporation or association shall possess drugs, prescriptions or poisons for the purpose of compounding, dispensing, retailing, wholesaling, or manufacturing, or shall offer drugs, prescriptions or poisons for sale at retail or wholesale unless registered by the department as a pharmacy, store, wholesaler, or manufacturer.

2. **Pharmacies.**

a. Obtaining a registration. A pharmacy shall be registered as follows:

(1) The application shall be made on a form prescribed by the department.

(2) The application shall be accompanied by a fee of one hundred dollars.

(3) To secure and retain a registration, a pharmacy must be equipped with facilities, apparatus, utensils and stocks of drugs and medicines sufficient to permit the prompt and efficient compounding and dispensing of prescriptions, as prescribed by regulation.

b. Renewal of registration. All pharmacy registrations shall be renewed biennially, in the month of January. The registration application shall be accompanied by a fee of fifty dollars. At the time of

biennial renewal, the owner of every pharmacy shall report under oath to the department any facts required by the board of pharmacy.

c. Display of registration. The registration shall be conspicuously displayed at all times in the pharmacy. The names of the owner or owners of a pharmacy shall be conspicuously displayed upon the exterior of such establishment. The names so displayed shall be presumptive evidence of ownership of such pharmacy by such person or persons. In the event that the owner of a licensed pharmacy is not a licensed pharmacist, the pharmacy registration issued shall also bear the name of the licensed pharmacist having personal supervision of the pharmacy. In the event that such licensed pharmacist shall no longer have personal supervision of the pharmacy, the owner shall notify the department of such fact and of the name of the licensed pharmacist replacing the pharmacist named on the license and shall apply for an amended registration showing the change. The amended registration must be attached to the original registration and displayed in the same manner. Both the owner and the supervising pharmacist shall be responsible for carrying out the provisions of this article.

d. Change of location. In the event that the location of a pharmacy shall be changed, the owner shall apply to the department for inspection of the new location and endorsement of the registration for the new location. The fee for inspection and endorsement shall be thirty dollars, unless it appears to the satisfaction of the department that the change in location is of temporary nature due to fire, flood or other disaster.

e. Conduct of a pharmacy. Every owner of a pharmacy is responsible for the strength, quality, purity and the labeling thereof of all drugs, toxic substances, devices and cosmetics, dispensed or sold, subject to the guaranty provisions of this article and the public health law. Every owner of a pharmacy or every pharmacist in charge of a pharmacy shall be responsible for the proper conduct of this pharmacy. Every pharmacy shall be under the immediate supervision and management of a licensed pharmacist at all hours when open. No pharmacist shall have personal supervision of more than one pharmacy at the same time.

f. A pharmacy as a department. When a pharmacy is operated as a department of a larger commercial establishment, the area comprising the pharmacy shall be physically separated from the rest of the establishment, so that access to the pharmacy and drugs is not

available when a pharmacist is not on duty. Identification of the area within the pharmacy by use of the words "drugs", "medicines", "drug store", or "pharmacy" or similar terms shall be restricted to the area licensed by the department as a pharmacy.

g. Limited pharmacy registration. When, in the opinion of the department, a high standard of patient safety, consistent with good patient care, can be provided by the registering of a pharmacy within a hospital, nursing home or extended care facility which does not meet all of the requirements for registration as a pharmacy, the department may waive any requirements pertaining to full-time operation by a licensed pharmacist, minimum equipment, minimum space and waiting area, provided that when the waiver of any of the above requirements is granted by the board, the pharmaceutical services to be rendered by the pharmacy shall be limited to furnishing drugs to patients registered for treatment by the hospital, and to in-patients for treatment by the nursing home or extended care facility. The initial registration fee and biennial renewal fee for a limited pharmacy shall be fifty dollars.

3. Registered store.

a. Obtaining a storekeeper's certificate. A registered store shall be licensed by the issuance of a storekeeper's certificate as follows:

(1) The application shall be made on a form prescribed by the department.

(2) The application shall be accompanied by a fee of fifteen dollars.

(3) No new certificate shall be issued to a store located within six miles of a registered pharmacy.

(4) The certificate may restrict the registered store to the sale of certain pre-packaged drugs as indicated on the certificate.

b. Renewal of certificate. All storekeeper's certificates shall be renewed biennially. The application shall be accompanied by a fee of fifteen dollars.

c. Termination of certificate. Any storekeeper's certificate may be terminated whenever a licensed pharmacy is established within a six-mile radius.

d. Change of location. In the event that the location of the store is changed, the owner must apply for a new certificate.

4. Wholesaler's or manufacturer's registration.

a. Obtaining a registration. A wholesaler or manufacturer shall be registered as follows:

(1) The application shall be made on a form prescribed by the department.

(2) The application shall be accompanied by a fee of two hundred fifty dollars.

b. Renewal of registration. All wholesalers' and manufacturers' registrations shall be renewed biennially in the month of September, at a fee of one hundred dollars for each place of business.

c. Display of registration. The registration shall be displayed conspicuously at all times in the place of business.

d. Change of location. In the event that the location of such place of business shall be changed, the owner shall apply to the department for inspection of the new location and endorsement of the registration for the new location. The fee for inspection and endorsement shall be one hundred dollars unless it appears to the satisfaction of the department that the change in location is of a temporary nature due to fire, flood or other disaster.

5. Inspection. The state board of pharmacy and the department of education, and their employees designated by the commissioner, shall have the right to enter any pharmacy, wholesaler, manufacturer, or registered store, or vehicle and to inspect, at reasonable times, such factory, warehouse, establishment or vehicle and all records required by this article, pertinent equipment, finished and unfinished materials, containers, and labels.

6. Revocation or suspension. A pharmacy, store, wholesaler, or manufacturer registration may be revoked or suspended by the committee on professional conduct of the state board of pharmacy in accordance with the provisions of article one hundred thirty.

7. Sale of drugs at auction. No controlled substance or substances and no poisonous or deleterious drugs or drugs in bulk or in opened containers shall be sold at auction unless the place where such drugs are sold at auction shall have been registered by the board, and unless such sale shall be under the personal supervision of a licensed pharmacist. Drugs in open containers shall not be sold at auction unless the seller shall have in his possession a certificate of the board showing that such drugs have been inspected and meet the requirements of this article. In the event that the drug so sold is one as to which this article or any federal statute or any regulation adopted pursuant to this article or an applicable federal statute require that the expiration date be stated on each package, such drug may not be sold at auction after such expiration date or when

such expiration date will occur within a period of thirty days or less from the date of sale.

§ 6808-a. **Identification of pharmacists.** Every pharmacist on duty shall be identified by a badge designed by the state board of pharmacy, which shall contain his name and title.

§ 6809. **Monetary penalties.** Any person holding a license, registration or certificate who violates any of the provisions of this article and who is not criminally prosecuted for a class A misdemeanor shall be subject to the money penalties provided in this section. When it shall appear to the committee on professional conduct that a violation of this article has occurred, a proceeding may be instituted which may result in a monetary penalty. In the latter instance, the licensee or registrant accused shall be given notice either personally or by registered mail to appear before a committee or panel consisting of five or more members which shall have power to fix the amount of such penalty not to exceed five hundred dollars for each violation. The sum shall be paid to the department. In the event that the accused shall deny such violation or shall fail to appear or shall fail to pay such penalty to the department within thirty days after the date when notice of the amount thereof is given to the accused by registered or certified mail, a proceeding may be instituted before the committee in accordance with article one hundred thirty of this title. If, by a four-fifths vote, the committee shall determine that the accused is guilty, the committee shall determine the amount of the penalty. The penalty may be sued for and recovered in the name of the people of the state of New York in an action brought by the attorney general. In such action, the findings and determination of the board shall be admissible evidence and shall be conclusive proof of the violation and the penalty assessed. Any person found guilty of a violation under the provisions of this section may institute a proceeding under article seventy-eight of the civil practice law and rules for the purpose of reviewing such determination returnable before the appellate division of the third judicial department.

§ 6810. **Prescriptions.** 1. No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health shall be distributed or dispensed to any person except upon a prescription written by a person legally authorized to issue such prescription. Such drug shall be

compounded or dispensed by a licensed pharmacist, and no such drug shall be dispensed without affixing to the immediate container in which the drug is sold or dispensed a label bearing the name and address of the owner of the establishment in which it was dispensed, the date compounded, the number of the prescription under which it is recorded in the pharmacist's prescription files, the name of the prescriber, the name and address of the patient, and the directions for the use of the drug by the patient as given upon the prescription. The prescribing and dispensing of a drug which is a controlled substance shall be subject to additional requirements provided in article thirty-three of the public health law. The words "drug" and "prescription required drug" within the meaning of this article shall not be construed to include soft or hard contact lenses, eyeglasses, or any other device for the aid or correction of vision.

2. A prescription may not be refilled unless it bears a contrary instruction and indicates on its face the number of times it may be refilled. A prescription may not be refilled more times than allowed on the prescription. The date of each refilling must be indicated on the original prescription. Prescriptions for controlled substances shall be refilled only pursuant to article thirty-three of the public health law.

3. A copy of a prescription for a controlled substance shall not be furnished to the patient but may be furnished to any licensed practitioner authorized to write such prescription. Copies of other prescriptions shall be furnished to the patient at his request, but such copies are issued for the informational purposes of the prescribers only, and shall be so worded.

4. Oral prescriptions for controlled substances shall be filled pursuant to article thirty-three of the public health law. A pharmacist may fill an oral prescription for a drug, other than a controlled substance, made by a practitioner legally authorized to prescribe drugs. An oral authorization for the refill of a prescription, other than a prescription for a controlled substance, may be made by a practitioner legally authorized to prescribe drugs. The pharmacist receiving such oral authorization for the refill of a prescription shall write on the reverse side of the original prescription the date, time, and name of the practitioner authorizing the refill of the prescription.

5. Records of all prescriptions filled or refilled shall be maintained for a period of at least five years and upon request made

available for inspection and copying by a representative of the department. Such records shall indicate date of filling or refilling, doctor's name, patient's name and address and the name or initials of the pharmacist who prepared, compounded, or dispensed the prescription. Records of prescriptions for controlled substances shall be maintained pursuant to requirements of article thirty-three of the public health law.

6. (a) Every prescription written in this state by a person authorized to issue such prescription shall be on prescription forms containing two lines for the prescriber's signature. There shall be a signature line in the lower right hand corner of the prescription form beneath which shall be clearly imprinted the words "substitution permissible"; there shall be a signature line in the lower left hand corner of the prescription form beneath which shall be clearly imprinted the words "dispense as written". The prescriber's signature on either signature line shall validate the prescription and shall designate approval or disapproval of substitution by a pharmacist of a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law. Imprinted conspicuously on the prescription forms shall be the words: "This prescription will be filled generically unless physician signs on line stating 'dispense as written'."

(b) If the prescriber designates approval of substitution he shall inform the patient that the pharmacist will substitute a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law.

(c) The provisions of this subdivision shall not apply to a hospital as defined in article twenty-eight of the public health law.

§ 6811. **Misdemeanors.** It shall be a class A misdemeanor for:

1. Any person knowingly or intentionally to prevent or refuse to permit any board member or department representative to enter a pharmacy or any other establishment for the purpose of lawful inspection;

2. Any person whose license has been revoked to refuse to deliver the license;

3. Any pharmacist to display his license or permit it to be displayed in a pharmacy of which he is not the owner or in which he is not employed, or any owner to fail to display in his pharmacy the license of the pharmacist employed in said pharmacy;

4. Any holder of a license to fail to display the license;
5. Any owner of a pharmacy to display or permit to be displayed in his pharmacy the license of any pharmacist not employed in said pharmacy;
6. Any person to carry on, conduct or transact business under a name which contains as a part thereof the words "drugs", "medicines", "drug store", "apothecary", or "pharmacy", or similar terms or combination of terms, or in any manner by advertisement, circular, poster, sign or otherwise describe or refer to the place of business conducted by such person, by the terms "drugs", "medicine", "drug store", "apothecary", or "pharmacy", unless the place of business so conducted is a pharmacy licensed by the department;
7. Any person to enter into an agreement with a physician, dentist, podiatrist or veterinarian for the compounding or dispensing of secret formula (coded) prescriptions;
8. Any person to sell or distribute any instrument or article, or any recipe, drug or medicine for the prevention of conception to a minor under the age of sixteen years; the sale or distribution of such to a person other than a minor under the age of sixteen years is authorized only by a licensed pharmacist but the advertisement or display of said articles, within or without the premises of such pharmacy is hereby prohibited;
9. Any person to manufacture, sell, deliver for sale, hold for sale or offer for sale of any drug, device or cosmetic that is adulterated or misbranded;
10. Any person to adulterate or misbrand any drug, device or cosmetic;
11. Any person to receive in commerce any drug, device or cosmetic that is adulterated or misbranded, and to deliver or proffer delivery thereof for pay or otherwise;
12. Any person to sell, deliver for sale, hold for sale, or offer for sale any drug, device or cosmetic in violation of this article;
13. Any person to disseminate any false advertisement;
14. Any person to refuse to permit entry or inspection as authorized by this article;
15. Any person to forge, counterfeit, simulate, or falsely represent, or without proper authority using any mark, stamp, tag, label

or other identification device authorized or required by rules and regulations promulgated under the provisions of this article;

16. Any person to use for his own advantage, or reveal, other than to the commissioner or his duly authorized representative, or to the court when relevant in any judicial proceedings under this article, any information acquired under authority of this article or concerning any method or process, which is a trade secret;

17. Any person to alter, mutilate, destroy, obliterate or remove the whole or any part of the labeling of, or the doing of any other act with respect to a drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded;

18. Any person to use on the labeling of any drug or in any advertising relating to such drug any representation or suggestion that an application with respect to such drug is effective under section sixty-eight hundred seventeen of this chapter or that such is in compliance with the provisions of such section;

19. Any person to violate any of the provisions of section sixty-eight hundred ten of this article;

20. Any person to violate any of the provisions of section sixty-eight hundred sixteen of this article;

21. Any person, to sell at retail or give away in tablet form bichloride of mercury, mercuric chloride or corrosive sublimate, unless such bichloride of mercury, mercuric chloride or corrosive sublimate, when so sold, or given away, shall conform to the provisions of national formulary XII. Nothing contained in this paragraph shall be construed to prohibit the sale and dispensing of bichloride or mercury in any form, shape, or color, when combined or compounded with one or more other drugs or excipients, for the purposes of internal medications only, or when sold in bulk in powder form, or to any preparation containing one-tenth of a grain or less of bichloride of mercury;

22. Any pharmacy to fail to properly post the list required by section sixty-eight hundred twenty-six of this article;

23. Any pharmacy to change its current selling price without changing the listed price as provided by section sixty-eight hundred twenty-six of this article;

24. Any person to refuse to permit access to or copying of any record required by this article; or

25. Any manufacturer to sell or offer for sale any drug not manufactured, prepared or compounded under the personal supervision of a chemist or licensed pharmacist or not labeled with the full name of the manufacturer or seller.

§ 6812. **Special provisions.** 1. Where any pharmacy registered by the department is damaged by fire the board shall be notified within a period of forty-eight hours, and the board shall have power to impound all drugs for analysis and condemnation, if found unfit for use. Where a pharmacy is discontinued, the owner of its prescription records shall notify the department as to the disposition of said prescription records, and in no case shall records be sold or given away to a person who does not currently possess a registration to operate a pharmacy.

2. Nothing in this article shall be construed as requiring the prosecution or the institution of injunction proceedings for minor violations of this article whenever the public interest will be adequately served by a suitable written notice of warning.

3. The executive secretary of the state board of pharmacy is authorized to conduct examinations and investigations for the purposes of this article through officers and employees of the United States, or through any health, food, or drug officer or employee of any city, county, or other political subdivision of this state.

§ 6813. **Seizure.** 1. Any drug, device or cosmetic that is adulterated, misbranded or may not be sold under the provisions of this chapter, may be seized on petition or complaint of the board and condemned in the supreme court of any county in which it is found. Seizure shall be made:

a. by process pursuant to the petition or complaint, or
b. if the secretary or other officer designated by him has probable cause to believe that the article

(1) is one which may not be sold under the provisions of section sixty-eight hundred seventeen of this chapter, or

(2) is adulterated, or

(3) is so misbranded as to be dangerous to health.

The article shall be seized by order of such officer. The order shall describe the article to be seized, the place where the article is

located, and the officer or employee making the seizure. The officer, in lieu of taking actual possession, may affix a tag or other appropriate marking to the article giving notice that the article has been quarantined and warning all persons not to remove or dispose of it by sale or otherwise until permission for removal or disposal is given by the officer or the court. In case of seizures or quarantine pursuant to such order, the jurisdiction of such court shall attach upon such seizure or quarantine, and a petition or complaint for condemnation shall be filed promptly.

2. The procedure for cases under this section shall conform as much as possible to the procedure for attachment. Any issue of fact joined in any case under this section shall be tried by jury on the demand of either party. The court at any time after seizure and up to the time of trial shall allow by order any party or his agent or attorney to obtain a representative sample of the condemned material, a true copy of the analysis on which the proceeding was based, and the identifying marks or numbers, if any, on the packages from which the samples analyzed were obtained.

3. Any drug, device or cosmetic condemned under this section shall be disposed of by destruction or sale as the court may direct after the decree in accordance with the provisions of this section. The proceeds of the sale, if any, shall be paid into the state treasury after deduction for legal costs and charges. However, the drug, device or cosmetic shall not be sold contrary to the provisions of this article. After entry of the decree, if the owner of the condemned articles pays the costs of the proceedings and posts a sufficient bond as security that the articles will not be disposed of contrary to the provisions of this article, the court may by order direct that the seized articles be delivered to the owner to be destroyed or brought into conformance with this article under supervision of the secretary. The expenses of the supervision shall be borne by the person obtaining the release under bond. Any drug condemned by reason of its being a new drug which may not be sold under this article shall be disposed of by destruction.

4. When the decree of condemnation is entered, court costs and fees, storage and other expense shall be awarded against the person, if any, intervening as claimant of the condemned articles.

5. In any proceeding against the board, or the secretary, or an agent of either, because of seizure, or quarantine, under this sec-

tion, the board or the secretary, or such agent shall not be liable if the court finds that there was probable cause for the acts done by them.

§ 6814. **Records of shipment.** For the purpose of enforcing provisions of this article, carriers engaged in commerce, and persons receiving drugs, devices or cosmetics in commerce or holding such articles so received, shall, upon the request of an officer duly assigned by the secretary, permit such officer, at reasonable times, to have access to and to copy all records showing the movement in commerce of any drug, device or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof: and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of drug, device or cosmetic to which such request relates: Provided, that evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: Provided further, that carriers shall not be subject to the other provisions of this article by reason of their receipt, carriage, holding or delivery of drugs, devices or cosmetics in the usual course of business as carriers.

§ 6815. **Adulterating, misbranding and substituting.** 1. Adulterated drugs. A drug or device shall be deemed to be adulterated:

a. (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations provided in this article.

b. If it purports to be, or is represented as, a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, qual-

ity or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or, in the absence or inadequacy of such tests or methods of assay, then in accordance with tests or methods of assay prescribed by regulations of the board of pharmacy as promulgated under this article. Deviations from the official assays may be made in the quantities of samples and reagents employed, provided they are in proportion to the quantities stated in the official compendium. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because (1) it exceeds the standard of strength therefor set forth in such compendium, if such difference is plainly stated on its label; or (2) it falls below the standard of strength, quality, or purity therefor set forth in such compendium if such difference is plainly stated on its label, except that this clause shall apply only to such drugs, or classes of drugs, as are specified in regulations which the board shall promulgate when, as applied to any drug, or class of drugs, the prohibition of such difference is not necessary for the protection of the public health. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia.

c. If it is not subject to the provisions of paragraph b of this subdivision and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

d. If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

e. If it is sold under or by a name not recognized in or according to a formula not given in the United States pharmacopoeia or the national formulary but that is found in some other standard work on pharmacology recognized by the board, and it differs in strength, quality or purity from the strength, quality or purity required, or the formula prescribed in, the standard work.

2. Misbranded and substituted drugs and devices. A drug or device shall be deemed to be misbranded:

a. If its labeling is false or misleading in any particular.

b. If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distribu-

tor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, that under clause (2) of this paragraph the board may establish reasonable variations as to quantity and exemptions as to small packages.

c. If any word, statement, or other information required by or under authority of this article to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

d. If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaïne, barbituric acid, beta eucaïne, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the secretary, after investigation, found to be, and by regulations under this article, or by regulations promulgated by the board, designated as, habit forming; unless its label bears the name and quantity, or proportion, of such substance or derivative and in juxtaposition therewith the statement "Warning — May be habit forming."

e. If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2) in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the kind and quantity by percentage or amount of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscyne, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: Provided, that, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the board.

f. Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or

application, in such manner and form, as are necessary for the protection of users: Provided, that, where any requirement of clause (1) of this paragraph, as applied to any drug or device is not necessary for the protection of the public health, the board shall promulgate regulations exempting such drug or device from such requirement.

g. If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided, that, the method of packing may be modified with the consent of the secretary in accordance with regulations promulgated by the board. Wherever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States, and not to those of the United States pharmacopoeia.

h. (1) If it is a drug and its container is so made, formed or filled as to be misleading; (2) if it is an imitation of another drug; (3) if it is offered for sale under the name of another drug; or (4) if it bears a copy, counterfeit, or colorable imitation of the trademark, label, container or identifying name or design of another drug.

i. If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.

j. Except as required by article thirty-three of the public health law, the labeling provisions of this article shall not apply to the compounding and dispensing of drugs on the written prescription of a physician, a dentist, a podiatrist or a veterinarian, which prescription when filled shall be kept on file for at least five years by the pharmacist or druggist. Such drug shall bear a label containing the name and place of business of the dispenser, the serial number and date of the prescription, directions for use as may be stated in the prescription, name and address of the patient and the name of the physician or other practitioner authorized by law to issue the prescription. In addition, such label shall contain the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.

§ 6816. Omitting to label drugs, or labeling them wrongly. 1.

(a) Any person, who, in putting up any drug, medicine, or food or preparation used in medical practice, or making up any prescription, or filling any order for drugs, medicines, food or preparation puts any untrue label, stamp or other designation of contents upon any box, bottle or other package containing a drug, medicine, food or preparation used in medical practice, or substitutes or dispenses a different article for or in lieu of any article prescribed, ordered or demanded, except where required pursuant to section sixty-eight hundred sixteen-a of this article, or puts up a greater or lesser quantity of any ingredient specified in any such prescription, order or demand than that prescribed, ordered or demanded, or otherwise deviates from the terms of the prescription, order or demand by substituting one drug for another, except where required pursuant to section sixty-eight hundred sixteen-a of this article, is guilty of a misdemeanor; provided, however, that except in the case of physicians' prescriptions, nothing herein contained shall be deemed or construed to prevent or impair or in any manner affect the right of an apothecary, druggist, pharmacist or other person to recommend the purchase of an article other than that ordered, required or demanded, but of a similar nature, or to sell such other article in place or in lieu of an article ordered, required or demanded, with the knowledge and consent of the purchaser. Upon a second conviction for a violation of this section the offender must be sentenced to imprisonment, for a term of not less than ten days nor more than one year, and to the payment of a fine of not less than ten dollars nor more than five hundred dollars. The third conviction of a violation of any of the provisions of this section, in addition to rendering the offender liable to the penalty prescribed by law for a misdemeanor, shall forfeit any right which he may possess under the law of this state at the time of such conviction, to engage as proprietor, agent, employee or otherwise, in the business of an apothecary, pharmacist, druggist, or to compound, prepare or dispense prescriptions or orders for drugs, medicines or foods or preparations used in medical practice; and the offender shall be by reason of such conviction disqualified from engaging in any such business as proprietor, agent, employee or otherwise or compounding, preparing or dispensing medical prescriptions or orders for drugs, medicines, or foods or preparations used in medical practice.

(b) The provisions of this section shall not apply to the practice of a practitioner who is not the proprietor of a store for the dispens-

ing or retailing of drugs, medicine and poisons, or who is not in the employ of such a proprietor, and shall not prevent practitioners from supplying their patients with such articles as they may deem proper, and except as to the labeling of poisons shall not apply to the sale of medicines or poisons at wholesale when not for the use or consumption by the purchaser: provided, however, that the sale of medicines or poisons at wholesale shall continue to be subject to such regulations as from time to time may be lawfully made by the board of pharmacy or by any competent board of health.

(c) The provisions of this section shall not apply to a limited pharmacy which prepares a formulary containing the brand names and the generic names of drugs and of manufacturers which it stocks, provided that it furnishes a copy of such formulary to each physician on its staff and the physician signs a statement authorizing the hospital to supply the drug under any generic or nonproprietary name listed therein and in conformity with the regulations of the commissioner of education.

2. For the purposes set forth in this section, the terms prescription, order or demand shall apply only to those items subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter. The written order of a physician for items not subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter shall be construed to be a direction, a fiscal order or a voucher.

§ 6816-a 1. A pharmacist shall substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded, provided that the following conditions are met:

(a) The prescription is written on a form which meets the requirements of subdivision six of section sixty-eight hundred ten of this article and the prescriber places his signature above the words, "substitute permissible", or in the case of oral prescriptions, the prescriber must expressly state that substitution shall be permitted; and

(b) The substituted drug product is contained in the list of drug products established pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law; and

(c) The pharmacist shall indicate on the label affixed to the immediate container in which the drug is sold or dispensed the

name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise. The pharmacist shall record on the prescription form the brand name or the name of the manufacturer of the drug product dispensed.

2. In the event a patient chooses to have a prescription filled by an out of state dispenser the laws of that state shall prevail.

§ 6817. **New Drugs.** No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug, unless

a. an application with respect thereto has become effective, or in the case of an investigational drug the sponsor has complied with the applicable requirements, under the federal food, drug and cosmetic act, or

b. when not subject to such act, such drug has been tested and has not been found to be unsafe or ineffective for use under the conditions prescribed, recommended or suggested in the labeling thereof, and, prior to selling or offering for sale such drug, there has been filed with the department an application setting forth

(1) full reports of investigations which have been made to show whether or not such drug is safe and effective for use;

(2) a full list of the ingredients used as components of such drug;

(3) a full statement of the composition of such drug;

(4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drugs;

(5) such samples of such drug and of the ingredients used as components thereof as the board or secretary may require; and

(6) specimens of the labeling proposed to be used for such drug.

2. An application provided for in paragraph b of subdivision one shall become effective on the one hundred eightieth day after the filing thereof, except that if the secretary or board finds, after due notice to applicant and giving him an opportunity for a hearing, that the drug is not safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, he shall prior to the effective date of the application, issue an order refusing to permit the application to become effective.

3. A drug dispensed on a written or oral prescription of a physician, dentist, podiatrist or veterinarian (except a controlled substance), shall be exempt from the requirements of this section if

such drug bears a label containing the name and place of business of the dispenser, the serial number and date of the prescription, directions for use as may be stated in the prescription and the name of the physician, dentist, podiatrist or veterinarian issuing the prescription and the name of the patient. In addition, such drug shall bear a label containing the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.

4. The board shall promulgate regulations for exempting from the operation of this section drugs (and with the concurrence of the commissioner of health, pursuant to article thirty-three of the public health law, controlled substances) intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs and labeled "For Investigational Use Only". Such regulations relating to the protection of the public health, provide for conditioning such exemptions upon:

a. The submission to the secretary before any clinical testing of a new drug is undertaken of reports by the manufacturer or sponsor of the investigation of such drug, of preclinical tests, including tests on animals of such drug adequate to justify the proposed clinical testing.

b. The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator or to clinics for administration to human beings; and

c. The establishment and maintenance of such records and the making of such reports to the board by the manufacturer or the sponsor of the investigation of such drugs of data including, but not limited to, analytical reports by investigators obtained as the result of such investigational use of such drug as the board finds will enable it to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subdivision one of this section.

5. This section shall not apply to any drug which was licensed under the federal virus, serum, and toxin act of July first, nineteen

hundred two (32 Stat. 728) or is licensed under section two hundred sixty-two of the public health service act of July first, nineteen hundred forty-four (58 Stat. 682), or under the federal virus, serums, toxins, antitoxins and analogous products act of March fourth, nineteen hundred thirteen (37 Stat. 832).

§ 6818. **Adulterated and misbranded cosmetics.** 1. A cosmetic shall be deemed to be adulterated:

a. If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: Provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon "Caution—this product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph e the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

b. If it consists in whole or in part of any filthy, putrid, or decomposed substance.

c. If it has been prepared, packaged, packed, shipped or held in any insanitary condition or in any other condition whereby it may have been rendered injurious to health.

d. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

e. If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by this article.

2. A cosmetic shall be deemed to be misbranded:

a. If its labeling is false or misleading in any particular.

b. If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations.

c. If any word, statement, or other information required by or under authority of this article to appear on the label is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions or purchase and use.

d. (1) If its container is so made, formed, or filled as to be misleading; or (2) if it bears a copy, counterfeit, or colorable imitation of a trademark, label, or identifying name or design of another cosmetic.

§ 6819. **Regulations making exceptions.** The board shall promulgate regulations exempting from any labeling requirement of this article drugs, devices and cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs, devices and cosmetics are not adulterated or misbranded under the provisions of this article upon removal from such processing, labeling, or repacking establishment.

§ 6820. **Certification of coal-tar colors for drugs and cosmetics.** The board shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.

§ 6821. **Poison schedules; register.** 1. The following schedules shall remain in force until revised by the board and approved by the department.

Schedule A. Arsenic, atropine, corrosive sublimate, potassium cyanide, chloral hydrate, hydrocyanic acid, strychnine and all other poisonous vegetable alkaloids and their salts and oil of bitter almond containing hydrocyanic acid.

Schedule B. Aconite, belladonna, cantharides, colchicum, conium, cotton root, digitalis, ergot, hellebore, henbane, phyto-lacca, strophanthus, oil of savin, oil of tansy, veratrum viride and their pharmaceutical preparations, arsenical solutions, carbolic acid, chloroform, creosote, croton oil, white precipitate, methyl or wood alcohol, mineral acids, oxalic acid, paris green, salts of lead, salts of

zinc, or any drug, chemical or preparation which is liable to be destructive to adult human life in quantities of sixty grains or less.

2. It shall be unlawful for any person to sell at retail or to furnish any of the poisons of schedules A and B without affixing or causing to be affixed to the bottle, box, vessel or package, a label with the name of the article and the word "poison" distinctly shown and with the name and place of business of the seller all printed in red ink together with the name of such poisons printed or written thereupon in plain, legible characters.

3. Manufacturers and wholesaler dealers in drugs, medicines, pharmaceutical preparations, chemicals or poisons shall affix or cause to be affixed to every bottle, box, parcel or outer inclosure of any original package containing any of the articles of schedule A a suitable label or brand in red ink with the word "poison" upon it.

4. Every person who disposes of or sells at retail or furnishes any poisons included in schedule A shall before delivering the same enter in a book kept for that purpose the date of sale, the name and address of the purchaser, the name and the quantity of the poison, the purpose for which it is purchased and the name of the dispenser. The poison register must be always open for inspection by the proper authorities and must be preserved for at least five years after the last entry. Such person shall not deliver any of the poisons of schedule A or schedule B until he has satisfied himself that the purchaser is aware of its poisonous character and that the poison is to be used for a legitimate purpose. The provisions of this paragraph do not apply to the dispensing of drugs or poisons on a doctor's prescription.

5. The board may add to or may delete from any of the schedules from time to time as such action becomes necessary for the protection of the public.

§ 6822. **Examinations and investigations.** The secretary is authorized to conduct examinations and investigations for the purposes of this article through officers and employees of the United States, or through any health, food, or drug officer or employee of any city, county or other political subdivision of this state, duly commissioned by the secretary as an officer of the board.

§ 6823. **Factory inspection.** For purposes of enforcement of this article, officers duly designated by the secretary are authorized:

(1) to enter, at reasonable times, any factory, warehouse or establishment in which drugs, devices or cosmetics are manufactured, processed, packed, or held, for introduction into commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such drugs, devices or cosmetics in commerce; and

(2) to inspect, at reasonable times, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

§ 6824. **Injunction proceedings.** In addition to the remedies hereinafter provided, the secretary is hereby authorized to apply to the court of the proper venue for an injunction to restrain any person from (a) introducing or causing to be introduced into commerce any adulterated or misbranded drug, device or cosmetic; or (b) from introducing or causing to be introduced in commerce any new drug which does not comply with the provisions of this article; or (c) from disseminating or causing to be disseminated a false advertisement, without being compelled to allege or prove that an adequate remedy at law does not exist.

§ 6825. **Proof required in prosecution for certain violations.** 1. In an action or proceeding, civil or criminal, against a person for violating such provisions of this article which relate to the possession of, compounding, retailing or dispensing of misbranded, substituted or imitated drugs, poisons or cosmetics, when it shall be necessary that an analysis be made for the purpose of establishing the quality of such drug, poison or cosmetic so as to determine the fact of misbranding, substituting or imitating, then it shall be required to prove at the trial or hearing of such action or proceeding, that the person, taking the same for analysis separated it into two representative parts, hermetically or otherwise effectively and completely sealed, delivered one such sealed part to the seller, manufacturer, wholesaler, pharmacist, druggist or storekeeper from whose premises such sample was taken and delivered the other part so sealed to the chemist designated by the state board of pharmacy; and the facts herein required to be proven shall be alleged in the complaint or information by which such action or proceeding was begun. The rules of the board shall be proven prima facie by the certificate of the secretary.

2. Any person accused of violation of any of the provisions of this article relating to adulterating, misbranding, substitution or im-

itation shall not be prosecuted or convicted or suffer any of the penalties, fines or forfeitures for such violation, if he establishes upon the hearing or trial that the drug, device or cosmetic alleged to be adulterated, misbranded, substituted or imitated was purchased by him under a written guaranty of the manufacturer or seller to the effect that said drug, device or cosmetic was not adulterated or misbranded, within the meaning of this article and proves that he has not adulterated, misbranded, substituted or imitated the same, provided the seller has taken due precaution to maintain the standard set for the drug, device or cosmetic. A guaranty, in order to be a defense to a prosecution or to prevent conviction or to afford protection, must state that the drug, device or cosmetic to which it refers is not adulterated, misbranded, substituted or imitated within the meaning of the provisions of this article and must state also the full name and place of business of the manufacturer, wholesaler, jobber or other person from whom the drug, device or cosmetic was purchased, and the date of purchase. The act, omission or failure of any officer, agent or other employee acting for or employed by any person within the scope of his authority or employment shall in every case be the act, omission or failure of such person as well as that of the officer, agent or other employee, and such person shall be equally liable for violations of this article by a partnership, association or corporation, and every member of the partnership or association and the directors and general officers of the corporation and the general manager of the partnership, association or corporation shall be individually liable and any action, prosecution or proceeding authorized by this article may be brought against any or all of such persons. When any prosecution under this article is made on the complaint of the board, any fines collected shall be paid into the state treasury as provided by this article.

3. No publisher, radio-broadcast licensee, advertising agency, or agency or medium for the dissemination of advertising, except the manufacturer, packer, distributor, or seller of the commodity to which the false advertisement relates, shall be subject to the penalties provided by this article by reason of the dissemination by him of any false advertisement, unless he has refused, on the request of the secretary, to furnish the secretary the name and post-office address of the manufacturer, packer, distributor, seller or advertising agency, who caused him to disseminate such advertisement.

§ 6826. **Posting.** 1. Every pharmacy shall post a list of drugs together with their current selling price in the manner prescribed by this section.

2. *a.* Such list shall be prepared from time to time by the board and distributed to each pharmacy in the state. The list shall be a compendium of the one hundred fifty most frequently prescribed drugs together with their usual dosages for which a prescription is required by the provisions of the "Federal Food, Drug and Cosmetic Act" (21 U.S.C. 301, et seq.; 52 Stat. 1040, et seq.), as amended; or by the commissioner of health.

b. Such list shall contain a notice in block letters not less than one inch in height which shall read: "Consult your pharmacist for the selection of the most economical drug product available to fill your doctor's prescription".

3. The board shall provide appropriate space on the list for inclusion by a pharmacy of its current selling price for each listed drug and dosage. The current selling price means the actual price to be paid by a retail purchaser to the pharmacy for any listed drug at the listed dosage.

4. The list shall be conspicuously posted at or adjacent to the place in the pharmacy where prescriptions are presented for compounding and dispensing.

5. Nothing contained herein shall prevent a pharmacy from changing the current selling price at any time, provided that the listed price is simultaneously adjusted to reflect the new current selling price.

MISCELLANEOUS PROVISIONS

TITLE I OF THE EDUCATION LAW

ARTICLE 3: UNIVERSITY OF THE STATE OF NEW YORK

§ 110. **Refunds.** 2. Applicants for professional licenses not receiving such licenses may be granted partial refunds not exceeding fifty percent of the fee paid to the department unless they have failed the examinations for such licenses, in which case such applicants may not receive a refund. Each applicant for a professional license who has at any time received a partial refund of an initial license application fee shall pay all required fees upon submitting any subsequent application for initial licensure.

ARTICLE 5. UNIVERSITY OF THE STATE OF NEW YORK

§ 212. **Fees.**

4. For the issuance of a replacement license, ten dollars.
5. For the replacement of a biennial registration certificate which has been lost or destroyed, or for the issuance of each registration certificate for more than one office, five dollars.
6. For a detailed certification of licensure record at the request of an individual, ten dollars.

RULES OF THE BOARD OF REGENTS

Part 3

THE UNIVERSITY OF THE STATE OF NEW YORK; STATE EDUCATION DEPARTMENT

§ 3.3 **Board of Regents disciplinary procedures.** The following rules shall apply to disciplinary proceedings brought pursuant to the provisions of Title VIII of the Education Law:

(a) The respondent shall be given at least twenty (20) days notice of the time and place of the meeting of the Regents Review Committee scheduled to review the results of respondent's disciplinary hearing.

(b) The respondent shall have twelve (12) days to file a brief with the Director of the Division of Professional Conduct. The original and ten (10) copies of respondent's brief shall be filed. The Assistant Attorney General may submit an answering brief, with a copy to respondent, at least one (1) day prior to the scheduled date for review.

(c) The time to be allotted to counsel for presentation of their arguments shall be determined by the Regents Review Committee.

(d) After the meeting of the Regents Review Committee, it shall transmit a written report of its review to the Board of Regents. The report shall be signed by the Chairman or by a majority of the members of the Regents Review Committee which reviewed the matter.

(e) The Commissioner of Education shall execute all orders in connection with disciplinary proceedings, as directed by the Board of Regents. Orders shall take effect as of the date of service except as otherwise provided.

(f) An application for reconsideration of a determination of the Board of Regents in disciplinary proceedings conducted pursuant to Education Law section 6510 may be made, in writing, at any time subsequent to the service of the order of the Commissioner of Education in accordance with such determination. No such application will be granted in the absence of a showing that the determination was rendered under a misunderstanding as to the facts, or was based on an error of law, or that there is new and material evidence which was not previously available, or that circumstances have occurred subsequent to the original determination which warrant a

reconsideration of the measure of discipline. The original and nine copies of each such application and all supporting papers shall be submitted to the Director of the Division of Professional Conduct, who shall deliver one copy to the Assistant Attorney General assigned to the case, and shall refer to the application to the Regents Review Committee or, if the determination was made pursuant to the provisions of article II-A of the Public Health Law to the Commissioner of Health. Oral argument on applications submitted to a Regents Review Committee will not be permitted, unless requested by such committee, but the respondent may submit evidence in affidavit form and a brief, and the Attorney General may submit answering affidavits and a brief within 20 days after receipt of the application. The Regents Review Committee or the Commissioner of Health shall submit recommendations in writing to the Board of Regents, which shall make the final determination on all such applications.

PART 17

DISCIPLINARY PROCEEDINGS IN THE PROFESSIONS

§ 17.1 **Complaints or other information.** All complaints or other information relating to licenses authorized to practice a profession under Title VIII of the Education Law shall be referred to the Director of the Division of Professional Conduct.

§ 17.2 **Investigation.** The Director of the Division of Professional Conduct or his designee shall, in matters involving possible professional misconduct, initiate an investigation of each such complaint or other information.

§ 17.3 **Charges.** Except as otherwise provided in paragraph (b) of subdivision 1 of section 6510 of the Education Law, the Director of the Division of Professional Conduct or his designee shall determine whether the results of the investigation will be referred to a panel of not less than three members of the state board for the appropriate profession which shall determine whether a charge of professional misconduct shall be brought. If the Director or his designee determine that the results of the investigation should not be so referred, he shall close the case.

§ 17.4 **Reports.** The Director of the Division of Professional Conduct or his designee shall submit a report by April 1st of each year on the status of cases investigated during the previous year, as well as on the disposition of any criminal or civil matters processed through his office, to the Chairman of the State Board for each of the professions supervised by the Board of Regents.

§ 17.7 **Consent orders.** Disciplinary proceedings conducted pursuant to the provisions of Title VIII of the Education Law may be disposed of in accordance with the following procedures:

(a) A respondent, other than a person subject to the provisions of section 230 of the Public Health Law, against whom charges have been voted, who wishes to admit guilt to at least one of the acts of misconduct alleged in the charges in full satisfaction of all charges in a pending disciplinary proceeding or who wishes not to contest the charges shall notify the Director of the Division of Professional Conduct and the Assistant Attorney General in charge of the Education Bureau of the Department of Law.

(b) If the Director of the Division of Professional Conduct or his designee, the Assistant Attorney General or his designee, a member designated by the panel of the State Board which voted the charges against the respondent and the respondent agree to the proposed admission of guilt in full satisfaction of all charges in the pending disciplinary proceeding or agree to a statement by respondent of no contest to the charges and also agree to the proposed penalty, a written application by the respondent shall be submitted to the Board of Regents, based upon the proposed penalty, consenting to the issuance of an order of the Commissioner of Education effectuating such penalty.

(c) The application shall be in such form and shall contain such substance as is acceptable to the Director of the Division of Professional Conduct or his designee, the Assistant Attorney General or his designee, and the designated member of the panel.

(d) With respect to the persons subject to the provisions of section 230 of the Public Health Law, the Board of Regents will entertain a recommendation of the Commissioner of Health with respect to a proposed admission of guilt or statement of no contest, in such form and containing such substance as is acceptable to the Commissioner of Health.

(e) In the event an application is not granted by the Board of Regents, nothing contained therein shall be binding upon the re-

spondent or construed to be an admission of any act of misconduct alleged in the charges and such application shall not be used against the respondent in any way. Any such application shall be kept in strict confidence during the pendency of the disciplinary proceeding. In addition, such denial by the Board of Regents shall be without prejudice to the continuance of the disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

(f) In the event the Board of Regents grants the application, the Commissioner of Education shall issue an order in accordance therewith.

§ 17.8 Surrender of license. Disciplinary proceedings conducted pursuant to the provisions of Title VIII of the Education Law may be disposed of in accordance with the following procedure:

(a) A licensee who is under investigation or a respondent against whom charges have been voted, who wishes to surrender his license to practice any of the professions enumerated in Title VIII, except for such persons subject to the provisions of section 230 of the Public Health Law, shall notify the Director of the Division of Professional Conduct or the Assistant Attorney General in charge of the Education Bureau of the Department of Law.

(b) An application to surrender a license shall be based upon a statement that the licensee admits or cannot successfully defend against one or more of the acts of alleged misconduct being investigated or, if charges have been voted, a statement that the respondent admits guilt to at least one of the acts of misconduct alleged in the charges, in full satisfaction of all charges in the pending disciplinary proceeding, or agrees not to contest the charges, or cannot successfully defend against one or more of the acts of misconduct alleged in the charges. If the Director or his designee and a member of the State Board for the profession agree to accept such statement of the licensee and, in a case in which charges have been voted, if the Assistant Attorney General or his designee also agrees to accept the statement of the respondent, a written application may be submitted to the Board of Regents for permission to surrender the applicable license. The application shall also contain such other statements and be submitted in such form and contain such substance as is acceptable to the Director.

(c) With respect to the persons subject to the provisions of section 230 of the Public Health Law, the Board of Regents will

entertain a recommendation of the Commissioner of Health upon a statement or application of the licensee or respondent, as the case may be, in such form and containing such substance as is acceptable to the Commissioner of Health and the State Board for Professional Medical Conduct.

(d) In the event the application is not granted by the Board of Regents, nothing contained therein shall be binding upon the licensee or the respondent or construed to be an admission of any act of misconduct investigated or alleged in the charges and such application shall not be used against the licensee or the respondent in any way. The application shall be kept in strict confidence during the pendency of the investigation or any other part of the professional misconduct disciplinary proceeding. In addition, any such denial by the Board of Regents shall be made without prejudice to the continuance of any disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

(e) In the event the Board of Regents grants the application, the Commissioner of Education shall issue an order in accordance therewith. The order shall include a provision that the licensee or the respondent, as the case may be, may not apply for the restoration of the license affected by the granted application until at least one year has elapsed from the date of the service of such order.

§ 17.9 **Violation of probation.** (a) Upon the receipt of information indicating that the respondent may be in violation of any of the terms or conditions of respondent's probation, the Department shall conduct an investigation which shall be initiated by the Director of the Division of Professional Conduct.

(b) The Director of the Division of Professional Conduct shall review the results of the investigation and, if in his judgment, he determines that a violation of probation proceeding is warranted, he shall give notice to the respondent, by letter, of the facts forming the basis of the alleged violation of respondent's probation. The respondent, in said letter, shall be requested to indicate whether there is any dispute as to the facts, and shall be informed that if respondent disputes any of the facts the respondent shall be entitled to a hearing thereon.

(c) If the respondent does not dispute the facts forming the basis of the alleged violation of probation, the matter shall be submitted to the Regents Review Committee for its review and recommendation(s) as to whether, based upon the undisputed facts,

there has been a violation of the terms or conditions of respondent's probation and, if so, as to the measure of discipline to be imposed upon the respondent.

(d) If the respondent disputes any of the facts forming the basis of the alleged violation of probation, the respondent shall be afforded a hearing before a hearing officer appointed by the Commissioner to hear and make findings of fact, conclusions of law, and recommendation(s). The Department shall give the respondent at least ten days notice of the hearing, fifteen if by mail. The evidence in support of the application shall be presented by counsel on behalf of the Department and the respondent shall also have the right to be represented by counsel. The Department and the respondent have the right to produce witnesses and other evidence, to cross-examine witnesses, and to examine any other evidence produced at the hearing. A stenographic record of the hearing will be made and the hearing officer shall not be bound by the rules of evidence, but the findings of fact and conclusions of law of the hearing officer shall be based upon substantial evidence.

(e) The report of the hearing officer shall be reviewed by the Regents Review Committee.

(f) The Regents Review Committee shall notify the respondent, at least seven days before its meeting, of the time and place of such meeting, and shall also notify the respondent of the opportunity of the respondent to appear in person and to be represented by counsel at such meeting.

(g) The Regents Review Committee shall transmit the report of the hearing officer and a written report of its review to the Board of Regents. The final determination shall be made by the Board of Regents and the Commissioner shall issue an order implementing such determination.

(h) The measure of discipline to be imposed for any violation of probation may be to continue the respondent on probation for a period in addition to the period of probation imposed in the original order, or to terminate the probation, vacate the stay of execution, and impose any measure of discipline authorized by section 6511 of the Education Law. A violation of probation shall constitute unprofessional conduct, and may constitute the basis for proceedings under either the provisions of section 6510 of the Education Law or of this Part.

§ 17.10 **Hearing Panels.** All rulings, findings of fact, determinations as to guilt, recommendations as to penalties to be imposed,

and any other action taken by a hearing panel in disciplinary proceedings shall be made by at least a majority vote, except for any determination of guilt which shall require a minimum of a four-fifths of the hearing panel.

§ 17.11 **Summary suspensions.** (a) If the director of the Division of Professional Conduct believes that the public health, safety or welfare imperatively requires emergency action against a professional license, certificate, registration, permit or other authorization of the licensee to practice under title VIII of the Education Law, the director may make an application, on behalf of the department, to the Board of Regents for the summary suspension of said authorization pending the institution and completion of formal disciplinary proceedings as provided under section 6510 of the Education Law.

(b) The director shall give the licensee at least five days' notice of an opportunity to be heard with respect to the application by the department for summary suspension. The notice shall be personally served upon the licensee or, if personal service cannot be made after due diligence, such notice may be served, by registered mail, at the licensee's last known address. The notice shall include a statement of the time, place and nature of the opportunity to be heard and a statement of the grounds asserted relative to the conduct of the licensee alleged to warrant summary suspension.

(c) Such application shall be heard by a regent designated by the chancellor for the purpose of said summary suspension proceeding. The application for summary suspension shall be presented by counsel on behalf of the department. The department shall have the burden of supporting its contention that the public health, safety or welfare imperatively requires emergency action. The licensee shall have the right to appear personally, to be represented by counsel, to submit affidavits and/or documentary evidence in response to the grounds asserted as the basis for the summary suspension, and to make an oral argument. No additional testimony will be taken and a transcript of the oral argument shall not be required.

(d) The regent designated by the chancellor to conduct the proceeding shall submit a written report of his conclusions and recommendation(s) to the Board of Regents, which shall determine whether to grant or deny the application for summary suspension. A determination by the Board of Regents granting the application must be based upon a finding that the public health, safety or welfare imperatively requires emergency action.

(e) Any determination of the Board of Regents shall be without prejudice to the department or licensee in any subsequent proceeding.

PART 24

PROFESSIONAL LICENSING

§ 24.1 **Committee on the Professions; procedures.** (a) The Committee on the Professions heretofore established by the Board of Regents, consisting of three department officers appointed by the Board of Regents, is continued and is hereby designated by the Board of Regents pursuant to chapter 130 of the Laws of 1969 to act on professional licensing applications in accordance with this Part.

(b) An applicant may apply to the Committee on Professions for reconsideration of its action. Upon such reconsideration the committee may modify its determination and shall notify the applicant of such determination. If upon reconsideration the Committee on Professions does not modify its action, the application shall be submitted to the Board of Regents for final determination.

(c) Petitions for the restoration or reinstatement of a professional license or certificate after review by the Committee on the Professions shall be submitted to the Board of Regents for determination. Such petitions shall be submitted in six copies, the original being signed and verified, and shall contain a concise statement of the circumstances leading to the loss of license or certificate, the petitioner's activities since such loss, and the steps taken toward rehabilitation. Five letters of reference in six copies each, the original being signed and verified, shall be submitted from individuals who have knowledge of the loss of license or certificate and the petitioner's subsequent activities. At least one year shall have elapsed from the date of service of the order of revocation or annulment, or the denial of restoration or reinstatement by vote of the Board of Regents, for the acceptance by the department of a petition to the Board of Regents for restoration or reinstatement of a license or certificate.

§ 24.3 **Professional qualifications.** As the equivalent of a professional program registered by the department, the Committee on the Professions may accept a professional program which is

(a) nationally accredited; or

(b) certified by an institution offering a program registered by the department to be the substantial equivalent of the registered program; or

(c) certified by an institution offering a nationally accredited program to be the substantial equivalent of the nationally accredited program.

§ 24.4 (e) For the admission of a graduate of a foreign pharmacy program to the theoretical portion (Part I) of the licensing examination in pharmacy, the Committee on the Professions shall require the completion of not less than three years of professional study of pharmacy or the equivalent culminating in the award of an acceptable degree or diploma in pharmacy from a school whose program meets standards satisfactory to the Department. Each graduate of a foreign pharmacy program who has passed Part I of the licensing examination in pharmacy shall be required to complete not less than twelve months of full-time experience in a registered pharmacy under the supervision of a registered pharmacist for admission to the practical portions (Parts II and III) of such examination.

§ 24.5 Indorsement of a professional license. (a) For full or partial indorsement of a license or certificate, the Committee on the Professions shall require eligibility for admission to the licensing examination, satisfactory performance on a licensing examination acceptable in whole or part to the appropriate board of examiners, . . . and the passing of such subjects, if any, of the New York State licensing examination which are considered necessary by such board to meet its standards, provided that a lesser period of professional experience or practice, or no professional experience or practice, shall be required where consistent with such requirements contained in the article of the Education Law relating to a particular profession.

(i) For the indorsement of a license to practice pharmacy issued by the licensing authority of another state of the United States, the Committee on the Professions shall require also that the applicant have either:

(1) one full year of experience in the practice of pharmacy within the five years immediately preceding the date of application and the successful completion of an oral examination administered by the Board of Pharmacy on the laws, rules and regulations pertaining to the practice of pharmacy in the State of New York; or

(2) successful completion of Parts II and III of the New York State licensing examination in pharmacy.

§ 24.8 **Determination of good moral character.** An applicant for authorization to practice a profession under title VIII of the Education Law may appeal to the Committee on the Professions for a review of an adverse determination, after a hearing, of a panel of the applicable professional State Board in accordance with the provisions of Part 28 of this Title. The provisions of subdivision (b) of section 24.1 of this Part shall not apply to any determination rendered by the Committee on the Professions under Part 28 of this title and such determination under Part 28 shall be final.

PART 28

DETERMINATION OF GOOD MORAL CHARACTER IN THE PROFESSIONS

§ 28.1 **Determination of good moral character.** The determination of whether an applicant for authorization to practice a profession under Title VIII of the Education Law is of good moral character shall be made in accordance with the procedures specified in this Part.

§ 28.2 **Information.** All information indicating that an applicant has been convicted of a crime or has committed an act which raises a reasonable question as to the applicant's moral character, shall be referred to the Director of the Division of Professional Conduct.

§ 28.3 **Investigation.** The Director of the Division of Professional Conduct shall arrange for a full and complete investigation of the circumstances surrounding such conviction or act. If the director determines that a reasonable question exists as to the applicant's moral character, then the director shall submit the results of the investigation, including any letters of reference from peers or others which may have been submitted by the applicant, to a panel of the appropriate professional state board for its review. The panel shall consist of three or more members of the state board.

§ 28.4 **Review.** Upon such review, the panel, by majority vote, may conclude in favor of the applicant to the effect that the moral character of the applicant is adequate for licensure, thereby fulfilling that licensure requirement, and the applicant and the Director of

the Division of Professional Licensing Services shall be notified of such conclusion by the Division of Professional Conduct. If, upon such review, the panel concludes, by a majority vote, that a substantial question exists as to the moral character of the applicant, the applicant shall be notified thereof. Upon the written request of the applicant, within 30 days after receipt of such notice, the Department shall schedule a hearing on such question.

§ 28.5 Hearing. The applicant shall be given 15 days notice, by mail, of the time and place of the hearing and a statement of the matters asserted which raised the question of the applicant's moral character. The applicant may be represented at the hearing by an attorney, may cross-examine witnesses, may produce witnesses, and may present evidence in support of the applicant's good moral character. The hearing, at which a verbatim record shall be taken, shall take place before a panel consisting of three or more members of the appropriate professional state board. The rulings and determination of the panel shall be made by a majority vote of the panel. The panel shall render a written report of its determination to the Director of the Division of Professional Licensing Services, a copy of which shall be forwarded to the applicant.

§ 28.6 Appeal. If the panel determines that the applicant has not fulfilled the licensure requirement of good moral character, the applicant may file a written notice of appeal therefrom with the Committee on the Professions within 30 days after service of the report of the panel upon the applicant. In the event the applicant does not appeal from the determination of the panel, the determination of the panel shall be final. In the event the applicant does appeal from the determination of the panel, the applicant may submit a brief to the Committee on the Professions and the Division of Professional Conduct within 30 days after filing the notice of appeal and an answering brief may be filed with the Committee on the Professions on behalf of the Department within 20 days after the receipt of the brief submitted by the applicant. The Committee on the Professions may affirm, reverse, or modify the determination of the panel and/or make such other determination as it may deem just and proper under the circumstances. The determination of the Committee on the Professions shall be final and a copy thereof shall be forwarded to the applicant.

§ 28.7 Reapplication. Whether or not the applicant appeals from the determination of the panel, the applicant may reapply for

licensure to the Director of the Division of Professional Licensing Services after the expiration of 18 months from the date of the service of the report of the panel.

PART 29

UNPROFESSIONAL CONDUCT

§ 29.1 General provisions for all professions.

(a) Unprofessional conduct shall be the conduct prohibited by this section. The provisions of these rules applicable to a particular profession may define additional acts or omissions as unprofessional conduct and may establish exceptions to these general prohibitions.

(b) Unprofessional conduct in the practice of any profession licensed or certified pursuant to Title 8 of the Education Law shall include:

(1) willful or grossly negligent failure to comply with substantial provisions of federal, state or local laws, rules or regulations governing the practice of the profession;

(2) exercising undue influence on the patient or client including the promotion of the sale of services, goods, appliances or drugs in such manner as to exploit the patient or client for the financial gain of the practitioner or of a third party;

(3) directly or indirectly offering, giving, soliciting, or receiving, or agreeing to receive any fee or other consideration to or from a third party for the referral of a patient or client or in connection with the performance of professional services;

(4) permitting any person to share in the fees for professional services, other than: a partner, employee, associate in a professional firm or corporation, professional subcontractor or consultant authorized to practice the same profession, or a legally authorized trainee practicing under the supervision of a licensed practitioner. This prohibition shall include any arrangement or agreement whereby the amount received in payment for furnishing space, facilities, equipment, or personnel services used by a professional licensee constitutes a percentage of or is otherwise dependent upon the income or receipts of the licensee from such practice, except as otherwise provided by law with respect to a facility licensed pur-

suant to Article 28 of the Public Health Law or Article 13 of the Mental Hygiene Law;

(5) conduct in the practice of a profession which evidences moral unfitness to practice the profession;

(6) willfully making or filing a false report, or failing to file a report required by law or by the Department of Education, or willfully impeding or obstructing such filing, or inducing another person to do so;

(7) failing to make available to a patient or client, upon request, copies of documents in the possession or under the control of the licensee which have been prepared for and paid for by the patient or client;

(8) revealing of personally identifiable facts, data or information obtained in a professional capacity without the prior consent of the patient or client, except as authorized or required by law;

(9) practicing or offering to practice beyond the scope permitted by law, or accepting and performing professional responsibilities which the licensee knows or has reason to know that he or she is not competent to perform, or performing without adequate supervision professional services which the licensee is authorized to perform only under the supervision of a licensed professional, except in an emergency situation where a person's life or health is in danger;

(10) delegating professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified, by training, by experience or by licensure, to perform them:

(11) performing professional services which have not been duly authorized by the patient or client or his or her legal representative;

(12) advertising or soliciting for patronage that is not in the public interest:

(i) Advertising or soliciting not in the public interest shall include but not be limited to advertising that:

(a) is false, fraudulent, deceptive, misleading, sensational or flamboyant;

(b) represents intimidation or undue pressure;

(c) uses testimonials;

(d) guarantees any service;

(e) offers gratuitous services or discounts in connection with professional services; but this clause shall not be construed to relate to the negotiation of fees between professionals and patients or clients, or to prohibit the rendering of professional services for which no fee is charged;

(f) makes claims of professional superiority which cannot be substantiated by the licensee, who shall have the burden of proof; or

(g) states or includes prices for professional services, except as provided for in clause (b) of subparagraph (ii) of this paragraph;

(ii) The following shall be deemed appropriate means of informing the public of the availability of professional services:

(a) informational advertising not contrary to the foregoing prohibitions; and

(b) the advertising in a newspaper, periodical or professional directory or on radio or television of fixed prices, or a stated range of prices, for specified routine professional services, provided that if there is an additional charge for related services which are an integral part of the overall service being provided by the licensee, the advertisement shall so state, and provided further that the advertisement indicates the period of time for which the advertised prices shall be in effect;

(iii) (a) all licensees placing advertisements shall maintain, or cause to be maintained, an exact copy of each advertisement, transcript, tape or videotape thereof as appropriate for the medium used, for a period of one year after its last appearance. This copy shall be made available for inspection upon demand of the Education Department or in the case of physicians, physician's and specialist's assistants, the Department of Health;

(b) A licensee shall not compensate or give anything of value to representatives of the press, radio, television or other communications media in anticipation of or in return for professional publicity in a news item;

(iv) No demonstrations, dramatizations or other portrayals of professional practice shall be permitted in advertising on radio or television;

(13) failing to respond within 30 days to written communications from the Education Department and to make available any relevant records with respect to an inquiry or complaint about the licensee's unprofessional conduct. The period of 30 days shall commence on the date when such communication was sent from the department

by registered or certified mail, with return receipt requested, to the address appearing in the last registration.

(14) violating any term of probation or condition or limitation imposed on the licensee by the Board of Regents pursuant to Education Law section 6511.

§ 29.2 General provisions for health professions.

(a) Unprofessional conduct shall also include, in the professions of:

medicine
acupuncture
physical therapy
physician's assistant
specialist's assistant
chiropractic
dentistry
dental hygiene
pharmacy
podiatry
optometry

ophthalmic dispensing
psychology
social work
massage
occupational therapy
speech pathology
audiology
nursing
(registered professional nurse,
licensed practical nurse);

(1) abandoning or neglecting a patient or client under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care, or abandoning a professional employment by a group practice, hospital, clinic or other health care facility, without reasonable notice and under circumstances which seriously impair the delivery of professional care to patients or clients;

(2) willfully harassing, abusing or intimidating a patient either physically or verbally;

(3) failing to maintain a record for each patient which accurately reflects the evaluation and treatment of the patient. Unless otherwise provided by law, all patient records must be retained for at least six years. Obstetrical records and records of minor patients must be retained for at least six years, and until one year after the minor patient reaches the age of 21 years;

(4) using the word "Doctor" in offering to perform professional services without also indicating the profession in which the licensee holds a doctorate;

(5) failing to exercise appropriate supervision over persons who are authorized to practice only under the supervision of the licensed professional;

(6) upon a patient's written request, failing to make available to a patient, or, to another licensed health practitioner consistent with that practitioner's authorized scope of practice, copies of the record required by paragraph (3) of this subdivision and copies of reports, test records, evaluations or X rays relating to the patient which are in the possession or under the control of the licensee, or failing to complete forms or reports required for the reimbursement of a patient by a third party. Reasonable fees may be charged for such copies, forms or reports, but prior payment for the professional services to which such records relate may not be required as a condition for making such records available. A practitioner may, however, withhold information from a patient, if, in the reasonable exercise of his or her professional judgment, he or she believes release of such information would adversely affect the patient's health, and this section shall not require release, to the parent or guardian of a minor, of records or information relating to venereal disease or abortion except with the minor's consent. This provision shall apply in lieu of section 29.1(b)(7) of this Part;

(7) guaranteeing that satisfaction or a cure will result from the performance of professional services;

(8) ordering of excessive tests, treatment, or use of treatment facilities not warranted by the condition of the patient;

(9) claiming or using any secret or special method of treatment which the licensee refuses to divulge to the State Board for the profession;

(10) failing to wear an identifying badge, which shall be conspicuously displayed and legible, indicating the practitioner's name and

professional title authorized pursuant to the Education Law, while practicing as an employee or operator of a hospital, clinic, group practice or multiprofessional facility, or at a commercial establishment offering health services to the public;

(11) entering into an arrangement or agreement with a pharmacy for the compounding and/or dispensing of coded or specially marked prescriptions;

(12) with respect to all professional practices conducted under an assumed name, other than facilities licensed pursuant to article 28 of the Public Health Law or article 13 of the Mental Hygiene Law, failing to post conspicuously at the site of such practice the names and the licensure field of all the principal professional licensees engaged in practice at that site (i.e., principal partners, officers or principal shareholders).

§ 29.7 **Special provisions for the profession of pharmacy.** (a) Unprofessional conduct in the practice of pharmacy shall include all conduct prohibited by sections 29.1 and 29.2 of this Part except as provided in this section, and shall also include the following:

(1) advertisements of the prices of prescription drugs which do not comply with the following provisions:

(i) the advertised price shall be in effect for a period of time stated in the advertisement;

(ii) when the pricing policy of a pharmacy provides for a variation from any advertised price for a special group, such as senior citizens, the advertising may include one price for which is applicable generally and another price which is applicable to the special group and which is so identified. Alternatively, the advertisement may state that the quoted prices are subject to a specific discount for individuals belonging to the special group;

(iii) when the advertising of prescription prices forms part of a larger advertisement which includes the offering of general merchandise, the advertising pertaining to prescription prices shall be separated physically, such as by a box, from the advertising pertaining to general merchandise;

(iv) nothing in this subdivision shall be construed to prevent the use in advertising of a statement to the effect that the price for which any prescription will be filled is available on request;

(v) such advertisement shall comply with the "Prescription Drug Consumer Price Listing" requirements set forth in section 200.200 of title 21 of the Code of Federal Regulations, as amended.

(2) failing to make prescription fee or price information readily available by providing such information upon request and upon the presentation of a prescription for pricing or dispensing. Nothing in this section shall be construed to prohibit the quotation of price information on a prescription drug to a potential consumer by telephone;

(3) using or substituting without authorization one or more drugs in the place of the drug or drugs specified in a prescription. Unauthorized use or substitution occurs if the same is done without the knowledge and consent of the prescriber. If other than the ingredients specified are utilized by the pharmacist in compounding or dispensing the prescriptions, improper substitution shall be presumed unless there shall be entered upon the reverse of the original prescription information setting forth the facts of the substitution, the date, time and manner in which authorization for substitution was given and the signature of the pharmacist who received such authorization;

(4) refilling a prescription for any drug for which a prescription is required by the laws of this State or of the United States, pursuant to the oral order of a prescriber, unless the oral order is reduced to writing and signed by the pharmacist receiving such order;

(5) placing in stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient; provided, however, that in a hospital, nursing home or extended care facility which has its own pharmacy and in which unit-dose medication is dispensed to inpatients, each dose being individually sealed and labeled with the name of the drug, dosage strength, manufacturer's control number and the expiration date, if any, the unused unit dose of medication may be returned to the pharmacy of the institution for redispensing;

(6) advertising or soliciting professional practice by means of providing physicians, or others authorized to prescribe, with prescription blanks imprinted with either the name of the pharmacist or the name of the pharmacy;

(7) nothing in this Part shall be construed to prevent the ownership of a firm or corporate practice in this State by an unlicensed person or persons or to prevent any contractual arrangement computing the salary of professional employees or the amount due the owner of such firm or corporation or a person leasing space or

equipment to such firm or corporation on the basis of a percentage of the receipts from the performance of professional services. This provision shall apply in lieu of section 29.1(b)(4) of this Part; and

(8) pharmacy records shall be maintained for five years unless otherwise required by law.

REGULATIONS OF THE COMMISSIONER OF EDUCATION

PART 51

ADMISSION TO PROFESSIONAL STUDY

§ 51.3 **Application for admission.** (a) An applicant for admission to a professional school in this State shall satisfy the preliminary education requirement prescribed by statute or by these regulations.

(b) An applicant for admission to a professional licensing examination shall submit evidence that he satisfied the preliminary education requirement before beginning his professional study and that such professional study, including experience, satisfied the requirement prescribed by statute or by these regulations.

(c) (1) An applicant for the indorsement of a license shall submit evidence that he satisfied the preliminary education requirement before beginning his professional study, that such professional study including experience, satisfied the requirements prescribed by statute or by these regulations and that the license is the original authority to practice and not an endorsement. The fee for indorsement shall be the same as the fee for license on examination.

(2) An applicant for admission to a professional school in this State or for admission to a licensing examination or for the indorsement of a license, whose application is based upon credit granted for the completion of courses of study in a country where English is not the language spoken, shall demonstrate his proficiency in English by passing an examination in English given by the department, or by submitting evidence of the completion of a satisfactory course of study in English or in such other manner as the commissioner shall determine.

(3) An applicant for admission to professional practice, who is not a citizen of the United States, shall submit, in such form and manner as the commissioner shall determine, satisfactory evidence that he has fully complied with all Federal and New York State statutes relative to the registration of aliens. No credential for admission to professional study or practice, no credit toward professional study or practice, and no admission to any examination shall be granted said applicant until evidence of such compliance has been accepted. Evidence of such compliance shall likewise be re-

quired of every applicant who has applied prior to the enactment of this regulation before further credit or any credential is granted him.

§ 51.4 **Administration of professional examinations.** (a) *Filing of applications.* Notwithstanding the provisions of the following sections relating to the filing of applications for admission to professional examinations [see Subchapter B hereof], any person seeking first admission to a licensing examination or readmission to a subsequent examination or part thereof in the same profession, shall file an application for admission to said professional licensing examination not less than 60 days before the examination. The associate commissioner for the professions may, in his discretion, waive the requirements of both the foregoing sentence and the following sections of these regulations relating to the time requirement for filing applications for admission to the professional licensing examinations [see Subchapter B hereof] upon proof being submitted that the person making application has been duly registered for military service under the Selective Service Act and has been notified to appear for induction into said military service, or upon the submission of sufficient evidence that the delay in applying for admission to a licensing examination was in no way due to the fault of the applicant, and provided the acceptance of such an application will not cause major alteration in the examination structure and procedure.

(b) *Identification.* For the purpose of identification the applicant shall present at the examination center a photograph as prescribed on the admission card and shall permit fingerprints to be taken.

(c) *Examination materials.* No candidate shall remove from the examination room any of the materials provided for the examination unless authorized to do so by the department representative. Such materials include examination booklets, answer sheets or score sheets, instructions and any reference tables or papers which were provided by the department and which may have been used in the course of the examination.

§ 51.5 (d) *Pharmacy.* For admission to study in pharmacy, a candidate shall present evidence of having satisfactorily completed at least 16 units in a registered four-year high school, including a minimum of 10 units in academic subjects, of which at least two units must be mathematics, or the equivalent as determined by the commissioner.

PART 63
PHARMACY

§ 63.1 **Professional study.** (a) The applicant shall meet the requirements of the Education Law, particularly section 6803. A course of study in pharmacology as required by section 6803 of the Education Law shall be considered completed only when certified as completed by the school in which such course was taken.

(b) The course of study in pharmacy school will not be approved if conditions in more than two subjects are allowed students for promotion from one year's class to the next. The work credited to a student in one pharmacy school shall not be accepted if at the time he was transferred the student had more than two conditions. Transfers from one school to another may be made only at the end of a school year.

§ 63.2 **Licensing examinations.**

(a) *General requirements.* (1) *Application.* An application for admission to a licensing examination shall be filed with the department as hereinafter prescribed. If the department finds that the application is complete and that all of the requirements of the statute and of these regulations have been met, it shall issue to the applicant an admission card which shall advise him of the time, date and place of the examination and shall admit him thereto. At the conclusion of the examination he shall return the admission card to the department representative conducting the examination.

(2) *Conduct of the examinations.* Licensing examinations shall be conducted in accordance with the following rules and any candidate violating such rules may be dismissed from the examination room by the department representative or otherwise disciplined.

(i) No candidate shall enter the examination more than 45 minutes after the question papers have been distributed nor shall any candidate leave the examination until 45 minutes have elapsed.

(ii) During the examination no candidate shall communicate with any other candidate in any way except upon the express permission of the department representative.

(iii) A candidate shall not bring books or help of any kind into the examination room unless directed to do so by the department because of the character of the examination.

(iv) After handing in his last paper in any examination each candidate shall make and subscribe to an affidavit to the effect that he has violated none of the rules.

(3) *Rating and report.* Upon the conclusion of each part of the examination the papers shall be rated under the general direction of the secretary of the board. The secretary of the board shall thereupon prepare his report and shall file the report promptly with the department. The rating of the examination shall not be completed until the report of the secretary has been filed. The department shall then notify each candidate of his success or failure and advise him, if he has failed, when and on what basis he may be re-examined.

(4) *Passing mark.* The passing mark in each part of the examination shall be 75 percent. However, when the examination is the objective type, the passing mark shall be 75 on a scale of 100. On this scale 100 shall represent the best performance possible. The passing point of 75 need not be an arithmetic percentage but may be set by the board at a predetermined mark which in the judgment of the board meets the minimum requirements for licensure.

(b) *Special requirements.* (1) The examination shall be held at such times and places as shall be determined by the commissioner.

The national examination of the National Association of Boards of Pharmacy may be used in whole or in part. Applications shall be filed with the department not less than 60 days before the examination. The examination shall consist of three parts:

Part I. Pharmacy, chemistry, pharmacology and applied mathematics

Part II. Economics, jurisprudence, posology, toxicology, Latin, ethics and professional conduct, prescription and nonprescription required drugs and prescription problems

Part III. Pharmaceutical preparations and pharmacy practice

(2) A candidate who passes any part of the examination shall not be re-examined in that part.

(3) Each applicant for admission to a complete examination must be verified by oath. It must show in a manner satisfactory to the department that the applicant:

(i) is more than 21 years of age and of good moral character;

(ii) is a citizen of the United States or has formally declared his intention of becoming such citizen;

(iii) has completed the preliminary education requirement described in subdivision (d) of Section 51.5 of this Title;

(iv) has completed the requirement in professional education described in Section 63.1 of this Part;

(v) has acquired at least six months of experience as a pharmacy intern in accordance with Section 257.3 of this Title except that graduates of nonregistered or nonaccredited foreign pharmacy programs shall meet the experience requirement as set forth in Section 24.4 (e) of this Title.

(4) A graduate of a registered school of pharmacy who has not completed the required practical experience or who is not 21 years of age may be admitted to part I of the examination only.

(5) A candidate who fails Part I of the licensing examination three times after December 1, 1977 shall be required to complete a program of study satisfactory to the department, in a school or college of pharmacy, in the subject areas included in part I of the licensing examination for subsequent readmission to part I.

§ 63.4 **Certification.** Any person, firm or corporation registered by the State Board of Pharmacy as a wholesaler or manufacturer may apply for and receive a certificate or certificates issued by the secretary of said board authenticating said registration, upon payment of a fee of two dollars for each said certificate.

PART 78

BIENNIAL REGISTRATION OF PROFESSIONAL PRACTITIONERS

§ 78.1 **Applications.** At least four months prior to the beginning date of the registration period, the department will mail to each licensed practitioner at his last recorded address an application for registration. A certificate of registration will be issued to each eligible practitioner who returns the completed application to the department with the fee required.

§ 78.2 **Registration dates.** Beginning dates for two-year registration periods for each professional shall be as follows:

- (a) In each odd-numbered year:
 - (1) January 1: pharmacy.

§ 78.3 **Display of registration certificate.** Registration certificates shall be conspicuously displayed by each practitioner in all

offices in which the following professions are practiced: chiropractic, dental hygiene, dentistry, massage, medicine, ophthalmic dispensing, optometry, osteopathy, pharmacy, physical therapy, podiatry, psychology and veterinary medicine. In instances where the practitioner serves in more than one professional office, duplicate registration certificates may be obtained upon making proper application to the department and submitting a fee of two dollars for each duplicate certificate required.

§ 78.4 **Registration changes.** Each professional practitioner shall notify the department of any change of name or address within 30 days of such change.

§ 78.5 **Failure to register.** Any practitioner who fails to register and who continues to practice or use restricted titles after the beginning date of the registration period in violation of Title VIII of the Education Law shall be subject to penalties as set forth in section 6502 of such law. Late registrants shall pay penalty fees in accordance with section 6502. Any practitioner who wilfully refuses to register shall be subject to the penalties set forth in section 6511 of such law.

MISCELLANEOUS PROVISION

PART 50

General

§ 50.2 Fees for special services. The department shall charge the following fees for special services rendered to individuals, provided that where delay in rendering the service may result in hardship for the individual, the fee may be collected after the service has actually been rendered;

(a) for the issuance of a replacement license, \$7.50;

* * *

(e) for the replacement of a biennial registration certificate which has been lost or destroyed, or for the issuance of each registration certificate for more than one office, \$2;

(f) for a detailed certification of licensure records at the request of an individual, \$5 in medicine, and \$3 in other professions;

RULES OF THE STATE BOARDS OF EXAMINERS

PART 257 PHARMACY

§ 257.1 [Pharmacy board.]

(a) *Officers, their powers and duties.* The officers of the board shall be a president, a vice president and the secretary.

(1) *President and vice president.* These officers shall be elected by ballot for the academic year. In case of the inability, neglect or refusal of the president to perform any duties of his office, the vice president shall perform such duties. The president may call meetings at such time and place as in his judgment the work of the board may demand; he shall call special meetings on the request in writing of three members of the board; at the annual meeting he shall appoint the standing committees, and he shall appoint such other committees as may be necessary for the proper carrying out of the provisions of the law and of the rules.

(2) *Secretary.* The secretary shall discharge the duties imposed on him by law, by rules and by the board; shall prepare the annual report for transmission to the Commissioner of Education by the first of October; shall notify the members in writing of all meetings of the board; shall be ex officio chairman of the questions committee; shall conduct the official correspondence of the examiners.

(b) *Quorum.* Five members shall constitute a quorum at the meetings of the board and two members shall constitute a quorum at the meetings of the violations committee.

(c) *Committees.* At the annual meeting the president shall appoint the following committees:

(1) *Violations committee.* Three committees of three members each—for Albany, for Buffalo, and for New York—shall be appointed to investigate alleged violations of the provisions of this article; to conduct hearings in respect thereto, and, when necessary, to bring the same to the attention of the Attorney-General. Meetings of such committees, when necessity exists, shall be held at the call of the secretary.

(2) *Examinations committee.* (i) The examinations committee shall consist of the secretary and such members of the board and others as the president shall appoint.

(ii) Other committees shall be appointed by the president at such times and for any purpose that may be found necessary for the proper enforcement of the provisions of the law.

§257.2 [Apprentice certificates.] (a) Pharmacy students may apply through their college for an apprentice certificate which shall be valid for a period of six years subsequent to date of issue.

(b) Students who have matriculated at a college of pharmacy outside New York State may make application through their employers for an apprentice certificate valid for a period of six years.

(c) *Supervision.* Not more than two registered apprentices shall be under the immediate and personal supervision of a licensed pharmacist.

§ 257.3 Pharmacy Internship.

(a) *Training Program.* An intern will be considered as having met the experience requirement for admission to the licensing examination if he completes an acceptable training program devoted to the preparing, compounding, preserving, dispensing or sale of drugs, medicines and therapeutic devices and to the performance of the functions related thereto under the supervision of a registered pharmacist.

(b) *Time Requirement.* (1) Graduates of registered or accredited programs shall be required to complete a minimum of six months of supervised training for admission to the full pharmacist licensing examination. The six months may be completed in accordance with the following:

(i) Up to three months in each of the summers preceding the final and the next to final years of a professional curriculum in pharmacy;

(ii) Any portion or all of the internship may be completed subsequent to graduation from a registered program in pharmacy or its equivalent.

(2) Graduates of non-registered or non-accredited foreign pharmacy programs shall meet the experience requirement as set forth in Section 24.4 (e) of the rules of the Board of Regents.

(c) *Preceptor Pharmacist.* The registered pharmacist who supervises an intern will be designated the preceptor pharmacist. Each preceptor pharmacist shall have practiced during the three years immediately preceding his assuming a preceptorship. The preceptor pharmacists shall have under his supervision not more than one full-time intern nor more than two part-time interns.

(d) *Additional Requirement.* In each pharmacy which will serve for the training of interns, one intern may be engaged for each 5000

prescriptions and for a major fraction thereof over a multiple of 5000 dispensed annually.

§ 257.4 **Examiners.** At least one examiner shall be present at part III of the examination of the candidates. Examiners may appoint one or more licensed pharmacists to act as assistants if it shall be necessary.

§ 257.5 **Care and conduct of pharmacy, drug store, manufacturer/wholesaler establishment and registered store.**

(a) To secure and retain registration a pharmacy or drug store must be equipped with facilities, apparatus, utensils and stocks of drugs and medicines sufficient to permit the prompt and efficient compounding of prescriptions. The facilities, apparatus, utensils and stocks of drugs and medicines shall include the following:

(1) A clean, well-ventilated room or space equipped with necessary laboratory tables with drawers and shelves; storage facilities and plumbing; suitable provision for safeguarding poisons and narcotic drugs; adequate facilities for heating, lighting and ventilating; hot and cold running water; clean and sanitary surroundings; apparatus for sterilizing solutions and containers; a stock of United States Pharmacopoeia, National Formulary and other commonly used chemicals, drugs, and preparations, sufficient to compound ordinary prescriptions as dictated by experience in the community where the pharmacy or drug store is located; a copy of the latest revision of the *United States Pharmacopoeia*, together with all supplements thereto and the latest edition of the *National Formulary*, together with all supplements thereto; and the latest edition of *Handbook 11* containing "Laws, Rules and Information" concerning the practice of pharmacy in New York State, the latest edition of the New York State Narcotics Act, and such other modern books on pharmacy, chemistry and materia medica as will enable the pharmacist to have ready access to information required in compounding prescriptions; compounding and manufacturing equipment, including pill tiles, ointment slabs, water baths, ring stand and rings, evaporating dishes, sieves, test tubes, beakers, pipettes, graduates capable of accurately measuring volumes from 5 minims to at least 1 pint and from 1 cc. to at least 500 cc., Wedgewood mortars and pestles and porcelain or glass mortars and pestles of assorted sizes, funnels, filter paper, stainless steel spatulas, and nonmetallic spatulas, glass rods, suppository molds or machine, empty capsules of various sizes, powder

papers, clear glass and amber glass prescription bottles, eye dropper bottles, collapsible tubes, ointment jars, labels; poison and narcotic record books; prescription files; thermometers for measuring temperatures from zero degrees to 250 degrees Centigrade; base scales and balance for bulk, medium and light weighing, at least one of which must be sensitive to 2/10 grain, apothecaries and avoirdupois weights from 1 grain to 1 pound; metric weights from .050 gram to 50 gram. The stock shall also include other drug items and devices, the sale of which is restricted by law to a registered pharmacy, or drug store, thus enabling the registered establishment to provide full professional pharmaceutical service.

(2) A refrigerator of a capacity ample to serve the needs of the particular pharmacy, and providing at all times a storage temperature of 0 degrees to 15 degrees Centigrade (32 degrees to 59 degrees Fahrenheit). The use of such refrigerator shall be confined to the storage of drugs.

(b) Any pharmacy or drug store approved for registration shall include a prescription department occupying at least 75 square feet of space, and including a prescription counter providing at least 10 square feet of free working surface. If more than one pharmacist is on duty at any time, the free working surface shall be increased by at least four square feet for each additional pharmacist. The prescription counter shall be kept clean, and free of all merchandise or other material not being currently used in the practice of compounding and dispensing. The space behind the prescription counter shall be sufficient to allow free movement within the area, and shall be kept free of obstructions. Such pharmacy or drug store, if operated as a department of a general merchandising establishment, department store or discount house, shall be permanently enclosed by a partition at least nine feet six inches in height, except where the ceiling is less than nine feet six inches in height in which case the partition shall be from floor to ceiling. Identification of this department by use of words "drugs", "medicines", "drug store" or "pharmacy" or similar term, or combination of terms, shall be restricted to the area registered by the Board except that nothing in this restriction shall prevent the placement on the exterior of such establishment of signs indicating the existence of a pharmacy therein. Such exterior signs may consist of the name of the registrant and/or the word "pharmacy"; provided, however, that when the word "pharmacy" is used, it may not be used in juxtaposition to a non-registered name. When such an exterior sign exists, the phar-

macy must be available for service and under the supervision of a pharmacist at all times that the establishment is open for business.

(c) *Cleanliness and Sanitation.* No certificate of registration shall be issued or continued for the conduct of a pharmacy, drug store, manufacturer/wholesaler, or registered store unless the premises of such pharmacy, drug store, manufacturer/wholesaler or registered store shall be equipped with proper sanitary appliances and kept in a clean and orderly manner.

(d) *Damage by fire.* Should any establishment registered by the board be damaged by fire the board shall be notified within a period of 48 hours.

(e) Repealed.

(f) Repealed.

(g) *Prescription records.* Records of all prescriptions filled or refilled shall be maintained in a prescription record book for a period of at least five years and upon request made available for inspection by a representative of the Board of Pharmacy. Such records shall indicate date of filling or refilling—physician's name—patient's name and address—and name or initials of pharmacist who prepared, compounded, or dispensed the prescription.

(h) Every pharmacist and every pharmacy intern shall wear a badge prepared in accordance with the following specifications while on duty as a pharmacist or a pharmacy intern respectively.

(i) The badge shall measure 1" × 3".

(ii) The background shall be white. Lettering shall be in black.

(iii) There shall be two lines of type on the badge. The name of the pharmacist or of the pharmacy intern shall constitute the first line. The title "Pharmacist" or "Pharmacy Intern" whichever is applicable, shall constitute the second line.

(iv) The name of the pharmacist or of the pharmacy intern shall appear on the badge in the same form as it appears on the license or on the limited permit whichever is applicable. When the name would be too long to fit on the badge, using the type specified herein, initials may be used for the middle name and for the first name, if necessary.

(v) Both the name and the title shall appear in Gothic type 5/32 inch high.

- (vi) The badge shall be worn, clearly visible, on the chest area.
- (vii) The badge may be worn only by a licensed pharmacist or a person holding a limited permit as a pharmacy intern.
- (viii) No other information or marking of any kind is to appear on the badge.

§ 257.6 **Storekeeper's certificate.** All certificates granted certified storekeepers shall contain a list of such articles as may be sold under this form of registration.

(a) *Fee.* The fee for storekeeper's certificate of permit and registration of store shall be \$5.

(b) *Poisons.* The following poisons sold by certified storekeepers must be sold in original packages only and must be put up by a licensed pharmacist whose name and business address must be displayed on the package: carbolic acid, tincture of iodine, tincture of aconite, and tincture of belladonna.

(c) *Prohibitions.* The sale by registered stores of chloral, cocaine, laudanum, morphine, opium, injectable material of any type or any drug item bearing the manufacturer's caution or warning label is prohibited. The sale of the articles mentioned in the certificate shall be limited to the time that the certified storekeeper is a resident of the village or place in which he resided at the time the certificate was issued, and shall not extend beyond the time and the store for which the certificate was issued.

§ 257.7 **Registration of manufacturer, wholesaler, bottler, or packer.**

(a) No manufacturer, wholesaler, bottler, or packer who sells drugs from opened containers or who manufactures or sells poisonous, deleterious or habit-forming drugs shall be registered pursuant to the provisions of subdivision 5 of section 6805 unless (except as provided in subdivision [b] of this section) a pharmacist licensed in New York State is present at all times when the establishment is open for business, nor shall any such manufacturer, wholesaler, bottler, or packer sell such potentially dangerous drugs except to those outlets properly licensed to sell the same.

(b) Wholesalers who do not manufacture, rebottle or repack drugs shall designate in writing to the Board of Pharmacy the name of a registered pharmacist, or otherwise qualified person or persons acceptable to the board, whose duty it shall be to supervise the sale

of all potentially dangerous or harmful drugs. One of such persons shall be present at all times when the establishment is open for business.

§ 257.8 **Removal of establishment.** When a registered pharmacy, drug store or manufacturer/wholesaler moves to another location, such registrant may have the change in location certified upon the face of the certificate on payment of the statutory fee of \$25, and provided an inspection of the new premises shall satisfy the Board that they are suitable for the conduct of the business so registered.

§ 257.9 **Substitute or duplicate licenses.** Substitute or duplicate licenses may be issued to persons legally licensed whose licenses have been lost or destroyed. A temporary certificate of the facts valid for not longer than one year from date of issuance may be given an applicant, pending the determination of the validity of his claim for a substitute or duplicate license.

§ 257.10 **Relief clerks.** A relief clerk must deposit his license with the secretary while using a card license.

§ 257.11 **Signs upon establishments.** The surname alone is not sufficient; either the full name of the proprietor or the initials of the proprietor's given names prefacing his surname, or the corporate name of the licensee, if such be a corporation, shall be placed upon the exterior of the premises where the pharmacy, drug store, manufacturer/wholesaler or store is located.

§ 257.12 **[Restriction on sale of drugs.]** All drugs except those proprietary drugs exempt under section 6816 of the Education Law shall be sold by a licensed pharmacist, a pharmacy graduate or a senior or junior pharmacy student under the supervision of a licensed pharmacist.

§ 257.13 **Sale of vaccines, viruses, serums, toxins, antitoxins, analogous products and other perishable drugs.**

(a) No person shall offer for sale, sell or give away or exchange in the State of New York any vaccine, virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention or treatment of diseases of man or animals, unless: (1) such vaccine, virus, serum, toxin, antitoxin or analogous product has been propagated and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Federal Security Administration,

to propagate and prepare such vaccine, virus, serum, toxin, antitoxin or analogous product for sale; nor (2) unless each package of such vaccine, virus, serum, toxin, antitoxin or analogous product has affixed thereto a label by the manufacturer stating the proper name of the article contained therein, the name, address and license number of the manufacturer, the lot number, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results. Provided, that the suspension or revocation of any license shall not prevent the sale, barter or exchange of any vaccine, virus, serum, toxin, antitoxin or analogous product which has been sold and delivered by the licentiate prior to such suspension or revocation, unless the owner or custodian of such vaccine, virus, serum, toxin, antitoxin or analogous product has been notified by the Federal Security Administration not to sell, barter or exchange the same.

(b) This section shall not apply to autogenous vaccines; nor shall it apply to any vaccine, virus, serum, toxin, antitoxin or analogous product or other perishable drug produced in a noncommercial research laboratory, to be used for scientific purposes only.

(c) No person shall have, keep, offer for sale or sell in the State of New York any such vaccine, virus, serum, toxin, antitoxin or analogous product or other perishable drug, later than the date marked upon the label by the manufacturer as indicative of the date beyond which the contents cannot be expected beyond reasonable doubt to yield specific results. Provided, that when the word "CONDEMNED" is legibly and conspicuously stamped or written in ink across the label of the package, it shall not be a violation of the subdivision.

(d) (1) No person shall sell or hold for sale any drug product, the nature of which requires storage under special conditions of temperature control as indicated either on the labeling, in the directions for storage of said product contained in an official compendium, or as dictated by common prudence, unless such special condition of temperature control shall have been complied with during the entire period of time in which such product has been held for sale.

(2) In the administration of this section the words "store in a cool place" or a phrase of like intent shall be construed to mean storage in a place, the temperature of which is maintained by mechanical control at a temperature not in excess of 59 degrees Fahrenheit.

(e) No person shall falsely label or mark any package or container of any vaccine, virus, serum, toxin, antitoxin or analogous product, or other perishable drug aforesaid, nor alter any label or mark on any package or container of any vaccine, virus, serum, toxin, antitoxin or analogous product or other perishable drug aforesaid so as to falsify such label or mark.

(f) No person shall repackage in its entirety or in part any vaccine, virus, serum, toxin, antitoxin or analogous product or other product of a perishable nature, unless all portions of such repackaged product shall bear its numerical count, the original control number, expiration date of the product, and the name and address of the original packer, as well as the name and address of the person so repackaging.

§ 257.14 **Sale of drugs at auction.** No drugs or drugs in bulk or in open containers shall be sold at auction unless the place where such drugs are sold at auction shall have been registered by the Board of Pharmacy, and such sale shall be under the personal supervision of a licensed pharmacist. Date, time and place of such auction must be filed at the board office at least seven days prior to the date of said auction. At such auction, drugs in bulk or in open containers may only be sold in one lot to a duly qualified pharmacy registrant who shall promptly remove such drugs to his establishment and the board office notified promptly as to the disposition of such drugs.

§ 257.15 **Repacking and dispensing of prescription required drugs.** No drug for which a prescription is required by the laws of this State, or of the United States, shall be repackaged for any purpose or dispensed except by a pharmacist registered in this State, or by a registered apprentice under the personal supervision of such a pharmacist. Labels shall bear sufficient information for proper identification and safety. Such drugs shall be dispensed only upon the prescription of a practitioner legally authorized to prescribe such drugs, and shall not be refilled unless there is a written record of authorization for refilling. Adequate repackaging, dispensing and refilling records must be maintained for a period of at least five years.

§ 257.16 [**Sales requiring prescriptions.**] All preparations of *sulfanilamide*, *cincophen*, *aminopyrine*, *amphetamine* (except for external use in combination with other ingredients unfit for internal

administration), *dinitroresol*, *dinitrophenol* or *thyroid*, their derivatives or mixtures containing sulfanilamide, cinchophen, aminopyrine, amphetamine (except for external use in combination with other ingredients unfit for internal administration), dinitroresol, dinitrophenol or thyroid, except such preparations containing these drugs or derivatives which in the expressed opinion of the Federal Food and Drug Administration have been or may from time to time be determined safe for general sale, shall be sold at retail for human consumption only upon the written prescription of a physician. The prescription shall remain on file in the pharmacy where compounded. Such prescription shall not be refilled if it bears indication by the physician that it is not to be refilled.

§ 257.17 **Drugs sold below official standard.** The sale of any drug that falls below the official standard as provided in the official compendiums is prohibited unless the manufacturer of such drug has received the approval of the board for the sale of such drug.

§ 257.18 **Names of drugs, statements, labeling, and directions for use.**

(a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term *drug defined in an official compendium* means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium or a standard work on pharmacology acceptable to the board differs in strength, quality or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.

(d) Among representatives in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or cosmetic.

(e) The labeling of a drug which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such drug in such labeling by a name which includes

or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(f) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as "Manufactured for and Packed by," "Distributed by;" or other similar phrase which expresses the facts. All drugs must be identified by a control number properly recorded by the manufacturer, packer, or distributor and must bear on each label of each package or container an expiration date if the need for such date has been determined by the manufacturer, by a Federal agency, or by this department.

(g) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(h) Where a person manufactures, packs or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(i) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

(j) (1) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of such drug in the package, exclusive of wrappers and other material packed with such drug.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight by measure, which are generally used by consumers and users of such drug to express quantity thereof and which give accurate information as to such quantity. But if no general usage in expressing accurate information as to the quantity of such drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampul or other unit form shall be in terms of weight if the drug is solid, semisolid or viscous, or in terms of measure if the drug is liquid; the statement of the quantity

of a drug which is in such unit form shall be in terms of numerical count of such units, supplemented, when necessary, to give accurate information as to the quantity of such drug in the package, by such statement (in such terms, manner and form as are not misleading) of the weight or measure of such units, or of the quantity of each active ingredient in each such unit, as will give such information.

(3) The statement of the quantity of a device shall be expressed in terms of numerical count.

(k) A statement of weight shall be in terms of the avoirdupois pound, ounce and grain, or of the kilogram, gram and milligram. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, fluid ounce and fluidram subdivisions thereof, or of the liter, milliliter or cubic centimeter, and shall express the volume of 68 degrees Fahrenheit (20 degrees Centigrade).

(l) Statements of the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(m) A word, statement or other information required by or under authority of article 137 of the Education Law to appear on the label may lack the prominence and conspicuousness required by reason (among other reasons) of:

(1) The failure of such word, statement or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase, the part or panel displayed;

(2) The failure of such word, statement or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement or information;

(4) Smallness or style of type in which such word, statement or information appears, insufficient background contrast, obscuring de-

signs or vignettes, or crowding with other written, printed or graphic matter.

(n) (1) The name of a substance or derivative required by or under authority of article 137 of the Education Law to be borne on the label of a drug shall be the name by which such substance is designated in such article, or such derivative is designated in regulations promulgated thereunder.

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in such article, shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(o) (1) If the drug is in tablet, capsule, ampul or other unit form, the statement of the quantity or proportions of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form, the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) The statement of the percentage of such substance or derivative contained in a drug shall express the percentage by weight; except that, if both the substance or derivative and the drug are liquid, the statement may express the percentage by volume at 68 degrees Fahrenheit (20 degrees Centigrade), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(p) The names and quantities or proportions of all such substances and derivatives, and the statement "Warning—May be habit forming," shall immediately follow (without intervening written, printed or graphic matter) the name by which drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(q) An abbreviation or chemical formula shall not be considered to be a common or usual name. The name "acetophenetidin" shall be considered to be the same as the name "acetphenetidin," "aminopyrine" the same as "amidopyrine." The name "alcohol," without qualification, means ethyl alcohol.

(r) (1) A derivative or preparation of a substance named in article 137 of the Education Law is an article which is derived or

prepared from such substance by any method including actual or theoretical chemical action.

(2) A statement on the label of a drug of the name of an ingredient thereof, which ingredient is a derivative or preparation of a substance named in such article, shall show the substance from which such ingredient is derived or prepared and that such ingredient is a derivative or preparation thereof.

(s) (1) If the drug is in tablet, capsule, ampul or other unit form, the statement of the quantity or proportion of a substance, derivative or preparation contained therein shall express the weight or measure of such substance, derivative, or preparation in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance, derivative or preparation in a specified unit weight or measure of the drug, or the percentage of such substance, derivative or preparation in such drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) A statement of the percentage of alcohol shall express the percentage of absolute alcohol at 60 degrees Fahrenheit (15.56 degrees Centigrade). A statement of the percentage of a substance, derivative or preparation other than alcohol shall express the percentage by weight; except that, if both the substances, derivative or preparation and the drug containing it are liquid, the statement may express the percentage by volume at 68 degrees Fahrenheit (20 degrees Centigrade), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(t) A label of a drug may be misleading by reason (among other reasons) of:

(1) The order in which the names of ingredients, substances, derivatives or preparations appear thereon, or the relative prominence otherwise given such names; or

(2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative or preparation, when such proportion or other fact is material in the light of the representation that such ingredient, substance, derivative or preparation is a constituent of such drug.

(u) A drug shall be exempt from the requirements of article 137 of the Education Law with respect to alkaloids, atropine, hyoscyne or hyoscyamine contained in such drug, if such alkaloid is contained

therein as a constituent of belladonna, hyoscyamus, scopola, stramonium or other plant material, or any preparation thereof, which was used as an ingredient of such drug, and no practical and accurate method of analysis exists for the quantitative determination of each such alkaloid in such ingredient. But such exemption shall be on the condition that the label of such drug shall state the quantity or proportion of total alkaloids contained therein as constituents of such ingredient.

(v) (1) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part or incorrect specification of:

(i) directions for use in all conditions for which such drug or device is prescribed, recommended or suggested in its labeling or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any there be, for which such drug or device is commonly and effectively used;

(ii) quantity of dose (including quantities for persons of different ages and different physical conditions);

(iii) frequency of administration or application;

(iv) duration of administration or application;

(v) time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factor);

(vi) route or method of administration or application; or

(vii) preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

(2) A shipment or other delivery of a drug device shall be exempt from compliance with the requirements of article 137 of the Education Law;

(i) with respect to directions for common uses, adequate directions for which are known by the ordinary individual;

(ii) if the label of such drug or device bears the statement "Caution: Federal law prohibits dispensing without a prescription", and all representations or suggestions contained in the labeling thereof with respect to the conditions for which such drug or device is to be used appear only in such medical terms as are not likely to be understood by the ordinary individual, and if such shipment or delivery is made for use exclusively by, or on the prescription of, physicians, dentists or veterinarians licensed by law to administer or apply such drug or device; but such exemption shall expire when such shipment or delivery, or any part thereof, is offered or sold or otherwise disposed of for any use other than by or on the prescrip-

tion of such a physician, dentist or veterinarian, except such use as renders the article not a drug or device within the meaning of such article 137; or

(iii) if the label of such drug or device bears the statement "For manufacturing use only", and the labeling thereof contains no representation or suggestion with respect to the effect of such drug or device, and if such shipment or delivery is made for use exclusively in the manufacture of another drug or device; but such exemption shall expire when such shipment or delivery, or any part thereof, is offered or sold or otherwise disposed of for any use other than in such manufacture, except such use as renders the article not a drug or device within the meaning of such article 137.

(3) The expiration of an exemption under this regulation shall not be considered to render invalid the exemption existing up to the time of expiration. The causing by any person of such exemption so to expire shall be considered to be an act of misbranding for which such person shall be liable.

(w) Label representation.

(1) If the label contains any representation in a foreign language, all words, statements and other information required by or under authority of article 137 of the Education Law to appear on the label shall appear thereon in the foreign language.

(2) If the labeling contains any representation in a foreign language, all words, statements and other information required by or under authority of such article to appear on the label or labeling shall appear on the labeling in the foreign language.

§ 257.19 [Misbranded and imitated drugs.]

(a) A drug or medicine shall be considered misbranded if labeled, sold or offered for sale under a name or title which deceptively imitates the official title of any drug or medicine that is listed in the National Formulary, United States Pharmacopoeia or United States Dispensatory.

(b) A drug or medicine shall be considered an imitation if in any way it deceptively imitates any official drug or medicine in the National Formulary, United States Pharmacopoeia or United States Dispensatory.

§ 257.20 [Cosmetics.]

§ [Labeling.]

(1) Among representations in the labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic, drug or device.

(2) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(3) If a cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such cosmetic, such as "Manufactured for and Packed by. . .," "Distributed by . . .," or other similar phrase which expresses the facts.

(4) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(5) Where a person manufactures, packs or distributes a cosmetic at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such cosmetic was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(6) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any cosmetic from the requirement that its label shall not be misleading in any particular.

(7) The statement of the quantity of the contents shall reveal the quantity of cosmetic in the package, exclusive of wrappers and other material packed with such cosmetic.

(8) A statement of weight or measure in the terms specified in article 137 of the Education Law may be supplemented by a statement in terms of the metric system of weight or measure.

(9) Unless an unqualified statement of numerical count gives accurate information as to the quantity of cosmetic in the package, it shall be supplemented by such statement of weight, measure or size of the individual units of the cosmetic as will give such information.

(10) A word, statement or other information required by or under authority of such article to appear on the label may lack that

prominence and conspicuousness required by such article by reason (among other reasons) of:

(i) the failure of such word, statement or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(ii) the failure of such word, statement or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(iii) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement or information;

(iv) insufficiency of label space (for the prominent placing of such word, statement or information) resulting from the use of label space for any word, statement, design or device which is not required by or under authority of such article to appear on the label;

(v) insufficiency of label space (for the prominent placing of such word, statement or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement or information, or to any design, or device; or

(vi) smallness or style of type in which such word, statement or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed or graphic matter.

(11) (i) All words, statements and other information required by or under authority of such article to appear on the label or labeling shall appear thereon in the English language.

(ii) If the label contains any representation in a foreign language, all words, statements and other information required by or under authority of such article to appear on the label shall appear thereon in the foreign language.

(iii) If the labeling contains any representation in a foreign language, all words, statements and other information required by or under authority of such article to appear on the label or labeling shall appear on the labeling in the foreign language.

(b) *Exempted cosmetics.* Permission for exemption from labeling for cosmetics during shipment or held for repacking may be obtained upon due application to the secretary.

§ 257.21. [Coal-tar products.]

(a) *Coal-tar regulations.* Such coal-tar colors as have been certified or may from time to time be certified under the provisions of the Federal Food, Drug and Cosmetic Act for use in drugs or for use in cosmetics shall constitute the list of certified dyes for use in drugs and cosmetics.

(b) The term *coal-tar hair dye* includes all articles containing any coal-tar color or intermediate which color or intermediate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

§ 257.22 [New drugs.]

(a) Newness of a drug may arise by reason (among other reasons) of:

(1) the newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating or other component;

(2) the newness for drug use of a combination of two or more substances, none of which is a new drug;

(3) the newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug;

(4) the newness of use of such drug in diagnosing, curing, mitigating, treating or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body; or

(5) the newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

(b) A shipment or other delivery of a new drug shall be exempt from the operation of article 137 of the Education Law if:

(1) the label of such drug bears the statement "For investigational use only";

(2) such shipment or delivery is made only to, and solely for investigational use by, an expert qualified by scientific training and experience to investigate the safety of drugs.

§ 257.23 [Habit-forming drugs.]

The chemical derivatives of substances which have been designated or may from time to time be designated under the provisions of section 502 (d) of the Federal Food, Drug and Cosmetic Act shall be considered as habit forming in accordance with section 6808 of the Education Law.

APPENDIX

Examinations

Examinations for licenses to practice pharmacy are held in Albany, Buffalo and New York. Full examinations are given in January and June of each year. Complete application materials should be submitted at least 60 days prior to the date of the examination.

Nature of the Examination

The examination is divided into three parts.

Part I consists of the National Association of Boards of Pharmacy's examinations (NABPLEX) in mathematics, pharmacology, chemistry and pharmacy. Two examinations are administered in the morning and two in the afternoon. The four examinations are written, objective type examinations. The competency statements upon which the examinations are based and sample questions may be found in the NABPLEX Candidate's Guide. The Guide may be obtained from the National Association of Boards of Pharmacy, One East Wacker Drive, Chicago, Illinois 60601 at a cost of seven dollars and fifty cents.

Part II A is the NABPLEX Practice of Pharmacy examination. Part II A is described in the Candidate's Guide (see above).

Part II B is an examination on New York State and applicable Federal law and prescription required and nonprescription required drugs. The examination consists of various item types such as short answer and matching but does not include essay items.

The two parts are administered in the morning and afternoon of the same day.

Part III is an examination in pharmacy practice. It may include the interpretation and evaluation of prescriptions, the identification of drugs, "errors and omissions", the identification and the directions for use of sick room supplies, the receipt of prescriptions by telephone, evaluation of drug therapy through the use of patient medication profiles and the compounding and dispensing of prescriptions. The examination is administered in two sessions, morning and afternoon on the same day.

Applicants may be admitted to the full examination after they have completed all of the requirements for admission. Graduates of accredited programs who meet all of the requirements except the internship requirement will be admitted to Part I. Upon completing the internship requirement, they will be admitted to Parts II and III.

Foreign graduates are admitted to Part I upon approval of their academic qualifications. After passing Part I, they are authorized to begin an internship. Upon the completion of a one-year internship acceptable to the Board, they will be admitted to Parts II and III of the examination.

Selected List of Other Laws Governing the Practice of Pharmacy

NEW YORK STATE

New York State Controlled Substances Act

Article 33 of the Public Health Law

Chapter II of the Administrative Rules and Regulations

Subchapter J, Part 80

Rules and Regulations on Controlled Substances

Information concerning and copies of the above may be obtained from:

New York State Health Department

Bureau of Narcotic Control

Fourth Floor — Tower Building

Empire State Plaza

Albany, New York 12237

Safe, Effective and Therapeutically Equivalent
Prescription Drugs (Required by Section 206,
subdivision (1), paragraph (o) of the Public
Health Law).

Copies may be obtained at a cost of \$2 from:

Health Education Service

P.O. Box 7126

Albany, New York 12224

FEDERAL

Comprehensive Drug Abuse Prevention and Control Act of 1970

Public Law 91-513

Information concerning and copies of the above may be obtained from:

U.S. Department of Justice

Drug Enforcement Agency

555 West 57th Street

New York, New York 10019

Federal Food, Drug and Cosmetic Act
as amended January 1971

Poison Prevention Package Act of 1970

Public Law 91-601

106

Code of Federal Regulations

Title 21

Food and Drugs

Copies of the above may be obtained from:

Superintendent of Documents

U.S. Government Printing Office

Washington, D.C. 20402

ACCREDITED COLLEGES OF PHARMACY IN NEW YORK STATE

Long Island University

Arnold and Marie Schwartz

College of Pharmacy and Health Sciences

75 DeKalb Avenue

Brooklyn, New York 11201

Dr. John J. Sciarra, Dean

(212) 330-2700

St. John's University

College of Pharmacy and Allied Health Professions

Grand Central and Utopia Parkways

Jamaica, New York 11439

Dr. Andrew J. Bartilucci, Dean

(212) 969-8000

State University of New York at Buffalo

School of Pharmacy

Cooke Hall

Amherst, New York 14260

Dr. Daniel Murray, Dean

(716) 636-2823

Union University

Albany College of Pharmacy

106 New Scotland Avenue

Albany, New York 12208

Dr. Walter Singer, Dean

(518) 445-7211